CHAPTER 6

SPECIAL PROCEDURES FOR LABORATORIES

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Program Background and Actions Related to Certification

The Survey Process and Related Activities

Other Activities

Section

Adverse Activities

Appeals of Adverse Actions

Appeals of Adverse Actions

Budget and Administration

Section

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6000. BACKGROUND

The Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, amended §353 of the Public Health Service Act (42 U.S.C. 263a), to extend jurisdiction of the Department of Health and Human Services (HHS) to regulate all laboratories that test human specimens for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. CLIA mandates that virtually all laboratories, including physician office laboratories, meet applicable Federal requirements and have a CLIA certificate in order to operate.

Regulations implementing CLIA are codified under 42 CFR Part 493. These regulations require that all laboratories or entities that perform laboratory testing:

- o Pay user fees as assessed by HCFA to finance the entire cost of administering the CLIA program;
- o Submit specific information to HHS or its designee;
- o Comply with specific administrative and program requirements;
- o Submit to surveys to assess compliance with CLIA requirements;
- o Be subject to specified enforcement actions; and
- o Apply for CLIA certificates based on the complexity of testing performed in the laboratory or based on accreditation by a HCFA-approved accreditation organization, or
- o In a State with a HCFA approved State laboratory licensure program, be licensed or approved in accordance with State requirements.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101-239, requires that laboratories participating in the Medicare program comply with CLIA requirements. Therefore, all laboratories, with the exception of laboratories licensed by a State with a HCFA-approved State laboratory licensure program (CLIA-exempt laboratories) must obtain a CLIA certificate to operate and to be eligible for payment under Medicare and Medicaid. Although CLIA-exempt laboratories do not need a CLIA certificate to operate, they are assigned a CLIA identification number for Medicare and Medicaid payment purposes.

6002. CLIA APPLICABILITY

The simplicity or volume of testing conducted does not exclude an entity from being subject to CLIA, but these factors determine which requirements a laboratory must meet for CLIA certification, and the fees to be paid by the laboratory. These requirements apply whether or not the laboratory or entity bills the patient for the services or is paid for the services by Medicare or Medicaid.

Certain types of laboratories and laboratory tests are NOT subject to meeting CLIA requirements. These include:

- o Any facility or component of a facility that performs testing strictly for forensic purposes;

o Research laboratories that do not report patient specific results (although they test human specimens) for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individuals;

o Components or functions of laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), formerly the National Institutes on Drug Abuse (NIDA) in which drug testing is performed that meets SAMHSA guidelines and regulations. (However, all other testing conducted by a SAMHSA certified laboratory is subject to this rule.);

o Laboratories under the jurisdiction of the Department of Veterans Affairs. Department of Defense (DOD) laboratories are subject to standards that HCFA has determined to be comparable to those in CLIA. DOD is responsible for assuring compliance with these requirements. (See §6022 for discussions on Federal laboratories.);

o Laboratory testing conducted in conjunction with the provision of home health or hospice care in an individual's home, where the home health agency or hospice employee merely assists the individual in performing a test, since tests performed by individuals in the home are not subject to CLIA;

o Laboratories licensed in a State whose laboratory licensure program is approved by HCFA, i.e., CLIA exempt;

o Facilities which serve only as collection stations. A collection station receives specimens to be forwarded to a laboratory performing diagnostic tests;

o Radiological facilities that perform only imaging procedures (e.g., x-rays, ultrasounds, Magnetic Resonance Imaging, Computerized Tomography);

o Facilities performing only physiological testing, e.g. spirometry, slit-lamp test for eyes; and

o Any facility or component of a facility that performs testing for drugs of abuse for employment purposes.

> NOTE : In the preamble to the January 19, 1993, Federal Register notice (HSQ-202-FC), the application of CLIA requirements to employee workplace drug testing subject to CLIA was deferred until the issue could be studied further. Until such time as a final determination is made, CLIA regulations do not apply to testing conducted for workplace drug testing for employment purposes, including components or functions of any employer entity that performs substance abuse testing for any purpose other than as part of a treatment program. The CLIA rules do not apply to testing that results in disciplinary, administrative, or legal action if the test result is positive, or to testing for the presence or absence of substances of abuse involving an employee. This would include employer testing programs, which might lead to disciplinary action, whether or not there is an associate referral to an employee assistance program (EAP). Positive tests that result in the employee's referral to an EAP do not make the EAP subject to CLIA unless the program actually does testing for substances of abuse itself as a part of a substance abuse treatment program. Testing for drugs of abuse is covered by CLIA when the testing is part of a treatment program.

If a laboratory is performing testing subject to CLIA and does not obtain the appropriate certificate, it is in violation of Public Law 100-578 §353 and subject to specified penalties. Such cases or suspected cases should be referred to the RO for referral to OIG. (See §6030.)

6004. CONSULTATIVE CLIA ACTIVITIES

Centers for Disease Control and Prevention (CDC) assists HCFA CO CLIA component in evaluating and approving proficiency testing programs, accreditation programs and State laboratory licensure programs.

Clinical Laboratory Improvement Advisory Committee.--HHS established a committee of experts in laboratory science. This committee provides scientific and technical advice and guidance to HHS regarding the need for, and the nature of:

- Revisions to the standards under which clinical laboratories are regulated;
- The impact on medical and laboratory practice of proposed revisions to the standards; and
- The modification of the standards to accommodate technological advances.

CDC oversees the Clinical Laboratory Improvement Advisory Committee and provides HCFA with any other required scientific and technical expertise.

6006. APPLICATION AND CERTIFICATE PROCESS

It is the responsibility of the laboratory to obtain and submit Form HCFA-116 and necessary personnel information for a CLIA certificate. A laboratory cannot perform testing or claim Medicare and/or Medicaid payment for services performed without a CLIA certificate.

1. Registration Certificate.--This is issued to any laboratory that applies for a certificate of compliance or certificate of accreditation, and pays a registration fee. Laboratories applying for a certificate of waiver or for a certificate for PPM procedures are not required to obtain a registration certificate, but apply directly for either of these two certificates. A registration certificate is temporary and indicates only that the laboratory is registered with HCFA and does not indicate approval or compliance with CLIA requirements. It permits the laboratory to operate until HCFA or its designee determines through a survey or verification of accreditation that all applicable requirements are met. A registration certificate is valid for up to two years or until a survey takes place, or verification of accreditation is complete. Registration certificates can be reissued if compliance has not been determined prior to the expiration date or if a laboratory requests an appeal of a sanction imposed as a result of noncompliance with one or more CLIA conditions, which does not pose immediate jeopardy. In the latter case, a registration certificate is reissued and remains effective until a decision is made by an Administrative Law Judge (ALJ) of the Departmental Appeals Board (DAB). All sanctions imposed against the registration certificate carry forth when reissued.

2. Certificate of Waiver.--A certificate of waiver is issued to a laboratory that performs only waived tests, and pays the appropriate fee. It is valid for a two-year period.

3. Certificate for Provider-Performed Microscopy (PPM) Procedures.--This is issued to a laboratory in which a physician or practitioner performs only the microscopy tests listed at 42 CFR §493.19(c) or performs only the listed microscopy tests in any combination with waived tests.

4. Certificate of Compliance.--This is issued or reissued to a laboratory determined through a survey to be in compliance with applicable requirements for laboratories performing tests of moderate and/or high complexity. A certificate of compliance is valid for a period of two years. A certificate of compliance may also be reissued to a laboratory that has one or more Condition-level deficiencies which do not pose immediate jeopardy as long as an alternative sanction is in place. If

a CLIA certificate of compliance is due to expire prior to a hearing date, it may be reissued if HCFA finds that conditions in the laboratory do not pose immediate jeopardy. It remains effective while awaiting the hearing decision. All sanctions imposed against the certificate carry forth when the certificate is reissued.

5. Certificate of Accreditation--It is effective the date the accreditation organization verifies to HCFA the accreditation status of the laboratory. This date can be no earlier than the accreditation organization's initial approval. An attachment to the certificate of accreditation will reflect the effective date for each specialty/subspecialty approved by the accreditation organization. This is also the effective date for Medicare/Medicaid payment for the accredited specialties/subspecialties. This date usually coincides with the certificate effective date.

Payment for newly added specialties/subspecialties will be effective when accreditation for the specialties/subspecialties is verified by the accreditation organization. The effective date for the added specialties/subspecialties will appear on the attachment next to the added specialties/subspecialties.

New laboratories (laboratories not currently registered or not registered as accredited laboratories) seeking a certificate of accreditation will be issued a registration certificate permitting them to operate until certificate fees are paid and accreditation by a HCFA approved accreditation organization is verified. On expiration, and after payment of appropriate fees, these certificates will be reissued with a new 2-year effective date unless HCFA is notified by the accreditation organization of a laboratory's nonaccreditation status.

In the event of a Condition-level noncompliance determination as a result of a random sample validation or complaint survey, a laboratory with a certificate of accreditation is subject to a full review by HCFA or its agent. A certificate of accreditation may be reissued to an accredited laboratory that is out of compliance at the Condition-level provided an acceptable PoC is received by HCFA or its agent, and the compliance does not constitute immediate jeopardy, even if a hearing is pending.

A. Partial Accreditation.--Laboratories with a mixture of HCFA-certified and accredited specialties/subspecialties will receive a certificate (of compliance) with the accreditation effective date associated with the applicable specialty/subspecialty and displayed as an attachment to the certificate. The laboratory will be billed for the compliance fees for the specialties covered by HCFA, and for the certificate of compliance.

B. Changing Accreditation Organizations.--Laboratories changing accreditation organizations mid-cycle will notify the SA. Changes will be reflected in the attachment to the certificate of accreditation that indicates, by specialty or subspecialty, the accreditation organization being used for CLIA compliance. The expiration date of the certificate will remain the same. The new accreditation organization will be responsible for assuring that the laboratory is in compliance with its requirements prior to granting full accreditation.

A laboratory changing from certificate of accreditation to certificate of compliance prior to expiration will have its certificate of accreditation terminated and survey authority transferred to the appropriate SA. The laboratory must pay the revised certificate fee as well as the applicable compliance fee.

A laboratory changing from a certificate of compliance to a certificate of accreditation remains under HCFA jurisdiction until any/all deficiencies are corrected. If the PoC has been accepted and all fees are paid (including the revised certificate fee), the lab may have its certificate of compliance changed to a certificate of accreditation.

6. Effective Date-- The effective date of the CLIA certificate for provider-performed microscopy procedures, registration certificate, or a certificate of waiver for new laboratories is the date the CLIA application is entered into the CLIA data system. The effective date of the CLIA certificate of compliance is the date the laboratory is surveyed and found in compliance with the CLIA requirements. The effective date of the CLIA certificate of accreditation is the date the organization verifies to HCFA that the laboratory is accredited by them. This date can be no earlier than the accreditation organization initial approval date. Once the effective date has been established, the laboratory's 2-year certificate cycle is set.

HCFA (directly or through its agents or contractors) is responsible for providing, collecting, and processing CLIA applications (see Exhibits 124 and 125); collecting registration and compliance fees; and entering application and fee data into the CLIA database. A HCFA contractor issues the CLIA certificate through the CLIA data system.

6008. LABORATORY LOCATION--CRITERIA FOR MEETING THE EXCEPTIONS

Each location where laboratory tests are performed must file a separate application to be separately certified unless it meets one of the following exceptions as outlined in 42 CFR 493.35(b), 493.43(b) or 493.55(b):

- Laboratories that are not at a fixed location, i.e., laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the CLIA certificate and address of the designated primary site or home base.

- Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests or PPM procedures per certificate) public health testing may file a single application.

- Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for CLIA certificate(s) for the laboratory sites within the same physical location or street address.

> NOTE: A primary site or home base is responsible for the day to day operation, supervision and administration of laboratory testing, including the employment of qualified personnel. Multiple sites are allowed under one certificate providing the laboratory director is identical for all affiliated testing sites.

Consider the following guidance for HHAs with multiple sites having the following options when applying for CLIA certification. Each site or office may apply for its own individual certificate, or multiple sites may apply for one CLIA certificate as long as these sites are under one provider number, i.e., parent branch. Since subunits by definition operate independently and have a unique provider number, each subunit must apply for a unique CLIA identification number.

6010. ASSIGNMENT OF CLIA IDENTIFICATION NUMBERS

CLIA identification numbers are 10 digit alpha-numeric numbers issued by the CLIA User Fee and Certificate Issuance System. This is assigned at the time of initial entry of the CLIA application and included with the mailing of the remittance fee coupon. Any number previously used for laboratory certification purposes is no longer valid. The 10-digit number consists of the following fields:

- Positions 1 and 2 in most cases identify the State in which the laboratory was located when it initially applied for a CLIA certificate. (A laboratory that relocates to another State retains its original CLIA number.);

- Position 3 is the alpha letter "D" to identify the provider/supplier as a laboratory under CLIA; and

- Positions 4 through 10 are the unique facility number identifiers.

Laboratories which are CLIA-exempt do not have a CLIA certificate, but are assigned a CLIA identification number using the 10-digit number.

Once a laboratory is assigned a number, it retains this number even if it withdraws from CLIA, has its license revoked, changes its certificate type or changes ownership, location (i.e., relocates to another State), name, or operator. A CLIA number will not be reassigned to another laboratory for any reason.

6012. CLIA USER FEE AND CERTIFICATE ISSUANCE SYSTEM

The CLIA database, which is a subsystem of Online Survey Certification and Reporting System (OSCAR), is a computerized subsystem that maintains data on every laboratory in the nation that is required to participate in the CLIA program. The database supports CLIA program operations, including the billing and collection of laboratory user fees, issuance of certificates, and the generation of reports.

A browse function is available for perusal of CLIA certificate data and laboratory accounts data. Browse allows authorized users to look through certificate/laboratory data and laboratory accounts data within the CLIA data base. A specific record from a list of available records or data for a specific laboratory within the data base may be selected. Data cannot be manipulated from this function. Standard or user defined reports that provide general information requested by users are available through the OSCAR system. To obtain directions on how to use the system, consult the OSCAR Report User's Guide or CO OSCAR Coordinator.

6014. CLIA INFORMATION IN OSCAR SYSTEM

OSCAR includes information on laboratories that participate under CLIA. Some of the information is comparable to what is collected in OSCAR on other suppliers of services and providers. Specifically, the entry and reporting of surveys, Federal surveys, and complaint investigations on CLIA laboratories are maintained in OSCAR's subsystems. In addition, data that are unique to laboratories participating in CLIA are collected in OSCAR. One subsystem is now available and is described below.

A. CLIA User Fee and Certificate Issuance Subsystem.--This subsystem maintains data on every laboratory in the United States (U.S.) and any foreign laboratory that tests U.S. specimens and that participates in the CLIA program. The system supports CLIA program operations including the collection of laboratory users' fees, the issuance of certificates, and the production of reports. Authorized users can query the certificate and laboratory accounts data. A specific record from a list of available records or data for an individual laboratory within the data base may be selected.

B. Additional Subsystems.--Additional subsystems will be developed in OSCAR to store and retrieve the following types of information:

- Laboratory applications;

- Proficiency testing information (e.g., enrollment and scores);

- Sanction activity and appeals;

- o Pertinent data from approved accrediting organizations; and
- o Pertinent data from CLIA-exempt State laboratory programs.

6016. REVISED CERTIFICATES

A. Revised Registration Certificate.--If, after a laboratory is issued a registration certificate, it changes its name, location, or director (operator), the laboratory must pay a fee to cover the cost of issuing a revised registration certificate. The fee for the revised registration certificate is based on the cost of issuing the revised certificate to the laboratory. Registration certificates do not require revision if there is a change (i.e., addition or deletion) of a specialty or subspecialty since this information is not reflected on the registration certificate.

B. Other Revised CLIA Certificates.--A laboratory must pay a fee to cover the cost of issuing a revised CLIA certificate other than a registration certificate in any of the circumstances listed below. A laboratory will be required to obtain a revised CLIA certificate if after a CLIA certificate is issued, a laboratory changes:

- o Location;
- o Director;
- o Name; or
- o Adds or deletes Services (e.g., specialty or subspecialty).

C. Certificate of Waiver.--If a laboratory with a certificate of waiver wishes to perform tests not listed in the waived test category, it must reapply and pay an additional fee for a certificate for PPM procedures or a registration certificate to cover the new testing. In the latter case, a compliance determination fee will also be assessed.

D. Certificate for Provider-Performed Microscopy (PPM) Procedures.--If a laboratory with a certificate for PPM procedures wishes to perform tests not listed in the PPM procedures category or the waived test category, it must reapply and pay an additional fee for a registration certificate to cover the new testing assessed. A compliance determination fee will also be assessed.

A change of ownership does not require a revised certificate unless one of the other changes specified above occurs.

6018. BILL ADJUSTMENTS

The RO/SA should contact the CO CLIA Component for current policy.

6020. REGIONAL OFFICE (RO) ROLE

The RO is responsible for:

- o The certification of Federal laboratories and some State operated laboratories within each region; (see §6022)
- o Oversight and monitoring of CLIA certification and enforcement activity for the States within the region, e.g., Performance of Federal monitoring surveys (FMS) (See §6232), Alternative Quality Assessment Survey Protocol (See §6112).
- o Performing validation and complaint surveys of laboratories in States whose laboratory licensure programs have been approved by HCFA.(See §§6200 - 6224)

6022. LABORATORIES UNDER DIRECT RO JURISDICTION

The following facilities fall under the direct jurisdiction of the RO. All survey and certification activities are to be performed by RO staff.

o Federal laboratories

Survey and Certification of Federal laboratories is the responsibility of the RO except as noted below:

- Laboratories owned or operated under the jurisdiction of the VA are subject to the requirements the VA establishes through rulemaking. They are not subject to CLIA requirements.

- Laboratories under the jurisdiction of the Department of Defense (DOD). DOD laboratories are subject to standards that HCFA has determined to be comparable to those in CLIA. DOD will be responsible for assuring their compliance with the CLIA requirements.

o Laboratories outside the United States

A laboratory outside the United States is also required to possess an appropriate CLIA certificate if it performs laboratory tests on human specimens referred to it by a CLIA laboratory in the U.S. or its territories. CO will determine survey responsibilities for laboratories located outside of the U.S. and its territories which must comply with CLIA requirements. For specific instructions for processing initial applications, see §6006.

o State operated laboratories

Laboratories owned or operated by the State represent a possible conflict of interest for survey purposes. Those State-operated laboratories where there is a conflict of interest will be surveyed by the RO.

The RO uses the following criteria to determine if a conflict of interest exists in State operated laboratories for CLIA survey and certification purposes.

o State surveyors work under the supervision of the same individual who is directly responsible for operating the State operated laboratory or laboratories; and/or

o State surveyors work in a State laboratory which is subject to CLIA.

A conflict of interest may not exist if the State funds local public health laboratories but does not operate them directly, or if one department of State government operates the laboratory and another department surveys them (e.g., Department of Public Health vs. Department of Mental Health).

Survey and certification functions are performed for laboratories under RO jurisdiction using the procedures in §§6100 - 6138 (monitoring of proficiency test scores) and Appendix C.

6024. RO REVIEW OF SA CERTIFICATION ACTIVITIES

CLIA has a single set of regulations applicable to all types of laboratories or entities performing laboratory tests based on test complexity. The RO is responsible for reviewing certification activity of the SA. The primary objective of this review is to ensure that the certification decision is supported by appropriate documentation that serves as sufficient evidence of the laboratory's compliance with the laws and regulations governing program participation.

In meeting this objective, the RO reviews several facets of the SA's entire certification process. Specifically, the RO review will ensure that the SA's:

- o Certification of compliance is consistent with the documented findings, taking into account the impact of deficient requirements on the respective conditions;
- o Recommendation of compliance or noncompliance is appropriate;
- o Interpretation of reasonable time and reasonable plans for the correction of deficiencies is appropriate;
- o Processing of CLIA certifications (including entering information into the CLIA database of Online Survey Certification and Reporting (OSCAR)) is efficient, accurate, and timely; and
- o Identify administrative/program problems at State, regional or national level.

In the event the RO determination disagrees with the SA, the decision must be supported by evidence. The RO justifies the determination in writing and attempts to resolve the disagreement. To foster continuous quality improvement, the RO communicates the resolution to CO. When a disagreement over interpretive policy cannot be resolved it should be referred to CO for resolution.

6026. STATE AGENCY (SA) ROLE

State agencies are responsible for survey and certification activity (including data entry) for non-Federal laboratories within its State. Lists of laboratories ready to be inspected are available to SAs through the CLIA database. The SA recommends to the RO whether to certify laboratories.

6028. CLIA LABORATORIES - COMPLIANCE WITH CIVIL RIGHTS REQUIREMENTS

CLIA laboratories are required to comply with certain requirements enforced by the Office for Civil Rights (OCR), including the Americans with Disabilities Act, but are not subject to traditional pre-certification assurance investigations. These requirements are enforced only on the basis of complaints. OCR makes any necessary investigations and determinations related to compliance with civil rights requirements.

The SA forwards complaints concerning a CLIA laboratory's noncompliance with Federal civil rights requirements to the RO. The complaint should be forwarded to OCR for review and investigation. As necessary, OCR forwards the complaint to the Department of Justice (DOJ) for evaluation, investigation, and disposition. Under no circumstances is the RO to investigate Federal civil rights complaints. OCR or the DOJ is responsible for investigating Federal civil rights complaints. HCFA is not authorized to bill the laboratory for the cost of a complaint survey for noncompliance with civil rights as part of the laboratory's fee obligation.

6030. REFERRALS TO THE OFFICE OF THE INSPECTOR GENERAL (OIG)

If a laboratory is operating without a CLIA certificate, the SA or RO as applicable, notifies the laboratory (see Exhibit 110) that it is violating CLIA requirements, and warns the laboratory of the consequences of such violations. The laboratory is afforded an opportunity to respond within 14 days. If it does not respond, or does not cease testing without a certificate within 30 days of the date of the notification to the laboratory, the RO will notify the OIG of the violation. The SA if applicable forwards documentation to the RO within 20 days of the date the violation notice was sent to the laboratory. In addition, the RO also refers to the OIG:

- o Cases of misrepresentation in obtaining a CLIA certificate;

o Laboratories that perform or represent the laboratory as entitled to perform tests not authorized by its CLIA certificate; and

o Laboratories that violated or aided or abetted in the violation of any provision of CLIA and its implementing regulations.

6032. NOTIFICATION OF CHANGE IN LABORATORY OPERATIONS

When a laboratory provides written notification of a change in location, director, laboratory name, technical supervisor and deletion of specialties or subspecialties, the SA enters the information into the HCFA data system and retains a copy of the laboratory's letter of request. The SA must not accept oral notices of change or intents to change. Once a compliance determination has been made on an addition of a specialty or subspecialty, the SA agency enters the information into the HCFA data system. For further information refer to §6104.

A change of ownership does not require a revised certificate unless one of the other changes specified above occurs. For information concerning change of ownership see §2005.

6034. MOBILE LABORATORIES

A mobile laboratory is defined as a movable, self-contained operational laboratory with its own personnel, equipment and records. It is not a vehicle that only transports laboratory equipment, supplies or personnel from one location to another, such as a vehicle used for transporting instruments, specimens and supplies to or from a health screening fair. Mobile laboratories:

o May file a single application for a registration certificate and CLIA certificate using the address of its home base; and

o Should obtain a separate certificate for each State in which testing is performed.

If a mobile laboratory operates in more than one State and does not obtain a separate certificate from each State, the SA contacts the RO to determine which State conducts the inspection.

A mobile laboratory may perform testing only when the laboratory is stationary. Concerns unique to mobile laboratories are addressed throughout Appendix C.

Each mobile vehicle and each laboratory that moves from testing site to testing site or has a temporary testing location, should provide SA with the home base or central dispatch phone number, so that an updated schedule of the location of testing and the hours of operation can be obtained.

Records may be maintained in the van or at the home base. Reports should reflect the home base address and indicate which mobile unit performed the test.

Mobile laboratory vans are distinguished by the vehicle identification number.

6036. FACILITIES WITH MULTIPLE SITES

A. Hospitals.--Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address. Hospital satellite or auxiliary laboratories located outside a hospital (at a different physical location or address) must each make a separate application. "Under common direction," means the hospital laboratory director is responsible for the quality of laboratory testing in all laboratories within the hospital that are covered by a single application and certification. "Street address" is the address assigned by the post office and is the physical location of the main laboratory. The street address may be different from the

mailing address, which can be a post office box or a billing address. For large hospitals, such as a university campus facility that may contain laboratories in separate buildings, the SA consults with the RO to determine if the hospital is eligible for a single certificate. A single individual may be named as director of up to five laboratories. A certificate may include more than one laboratory using the above criteria. The SA refers questions regarding multiple sites status to the RO.

The SA surveys in its entirety each laboratory site within a hospital seeking a single certification for all applicable conditions and standards. Proficiency testing (PT) is the only exception. Every laboratory site within a hospital is not necessarily required to perform PT. However, all analytes tested within the hospital laboratory's certification must be enrolled in an appropriate PT program. Appendix C has additional guidance concerning PT coverage at multiple sites.

Each certified laboratory must have a comprehensive quality assurance (QA) program designed to continually monitor and evaluate the overall quality of testing. The SA verifies that the laboratory QA program includes all laboratory testing locations covered under the laboratory's certification.

B. Laboratories Doing Limited Public Health Testing.--Not-for-profit or Federal, State, or local government laboratories with multiple sites that engage in limited public health testing may file a single application for a certificate regardless of the physical location. Multiple laboratories may be covered under one certificate as long as they are not-for-profit or Federal, State, or local government laboratories and collectively perform no more than any 15 tests categorized as moderate or waived. Laboratories doing limited public health testing, as defined above, should obtain a separate certificate for each State in which testing is performed. If a laboratory system performing limited public health testing operates in more than one State and does not obtain a separate certificate from each State, the SA contacts the RO to determine which State conducts the inspection. The laboratories may choose to apply for more than one certificate, and may want to do so based on the ramifications of any PT failures (for moderately complex tests), or any deficiencies cited during a compliance survey which would in any way limit the laboratory's certificate.

Not-for-profit or Federal, State, or local government laboratories that perform high complexity testing must file a separate application for certification for each laboratory performing high complexity testing regardless of their profit or government status.

Each separate location of a not-for-profit or Federal, State, or local government laboratory covered under a single certificate must meet all the applicable requirements of 42 CFR 493. The only exception is Subpart H, Participation in PT. All specialties, subspecialties, analytes or tests performed by that public health laboratory system must be enrolled in an approved PT program, if one is available. At the laboratory's discretion, PT samples may be distributed to all testing locations, restricted to certain locations, or performed at one location. (See Appendix C)

At a minimum, the SA verifies that all laboratory sites are included in a laboratory's comprehensive QA program which monitors the correlation of site's results with the instruments, test systems, and methods covered by the PT program. Failure of a laboratory to monitor and evaluate the quality of testing at each location is a deficiency.

C. Temporary Testing Sites.--The SA surveys temporary testing sites of laboratories under a single certificate, including mobile units and should make every effort to schedule the survey to coincide with testing.

6038. TRANSFUSION SERVICES COVERED BY HCFA/FDA MEMORANDUM OF UNDERSTANDING

HCFA and the FDA have a memorandum of understanding (MOU) that defines survey activities for facilities performing immunohematology (bloodbank) testing and transfusion services that are subject to HCFA (CLIA/Medicare/Medicaid) and FDA regulations. HCFA is responsible for inspecting

nonaccredited transfusion service facilities and reference laboratories formerly inspected by FDA and recording findings relative to CLIA/Medicare/Medicaid and FDA regulations.

A. Facilities Surveyed By The State Agency.--Survey facilities performing any immunohematology testing, not covered under the MOU, including hospitals, clinics, physician office laboratories (POLs), or donor centers as well as reference laboratories. In addition to all other required survey forms, the SA uses the Blood Bank Inspection Checklist and Report (Form HCFA-282 also known as FDA Form 2609) (Exhibit 123) to record survey findings of FDA requirements in applicable facilities.

FDA continues to inspect hospital transfusion services and reference laboratories covered under CLIA for purposes related to the manufacture of blood and blood products, i.e., collection of blood, if they:

o Collect blood and blood components in other than emergency situations, including autologous donations;

o Perform therapeutic collection or pheresis and no resulting product is used for further manufacturing; or

o Prepare frozen, deglycerolized, washed, rejuvenated, or leukocyte-poor red blood cells and/or recovered human plasma.

Facilities performing services that do not include transfusion services, but are performing laboratory testing on donor blood for purposes of manufacturing a product for transfusion (i.e., donor centers, plasmapheresis centers), must comply with both FDA and CLIA regulations. FDA conducts its portion of inspections in those facilities while HCFA surveys those facilities for compliance with the CLIA regulations.

Some facilities that are not accredited that perform blood banking or transfusion services may be subject to surveys by both the SA and FDA if they also perform procedures related to the manufacture of blood and blood products as described above. In these instances, the SA performs a CLIA survey relative to all testing being performed, i.e., patient and donor testing, and incorporates the FDA requirements outlined in Form HCFA-282 for compatibility testing, transfusion reactions, storage and distribution, and laboratory testing (Parts B, H, and I). FDA inspects for its blood collection, processing, and shipping requirements relative to the manufacture of blood and blood products in these facilities.

B. HIV, Hepatitis, and Syphilis Testing.--HCFA is responsible for the survey and certification of reference laboratories performing HIV, hepatitis, and syphilis testing for registered (unlicensed by FDA) blood establishments even though these laboratories are also subject to FDA regulation. Facilities testing for HIV antibody, hepatitis B surface antigen and syphilis for purposes of blood product preparation must meet all requirements for CLIA certification as well as FDA requirements. The SA uses the Form HCFA-282 (Part B) to record survey findings of FDA requirements.

Below are the relevant portions of FDA's requirements cross-referenced to CLIA for immunohematological, HIV, hepatitis, and syphilis testing:

	FDA	HCFA (CLIA)
Immunohematological Testing	21 CFR 606 21 CFR 610.53 21 CFR 640 Subparts A,B,C,D and F	42 CFR 493.1273

HIV	21 CFR 610.45	42 CFR 493.1241(d)(1)
Hepatitis Testing	21 CFR 610.40	42 CFR 493.1241(d)(2)
Syphilis Testing	21 CFR 640.5(a)	42 CFR 493.1239(e)

The HIV, hepatitis and syphilis testing requirements above do not require transfusion service facilities to retest blood for HIV, hepatitis and syphilis if the blood has already been tested in another CLIA certified facility (e.g., Red Cross or Community Blood Center).

6040. TRANSFUSION-RELATED FATALITIES

Facilities, including laboratories, involved in the collection or transfusion of blood or blood products must report transfusion-related fatalities to FDA, Center for Biologics Evaluation Research, Office of Compliance, at (301) 594-1191. FDA notifies HCFA CO when an investigation by HCFA is required. CO, in turn, informs the RO to authorize a survey of the facility and/or laboratory as applicable, regardless of the facility's accreditation status or CLIA exemption. This survey may be performed by either the RO or SA. The RO or SA will schedule and conduct the survey within 45 days of the notice from CO and submit a report of investigation to CO within 60 days of the survey. (See Appendix C, III, Investigation of Transfusion-Related Fatalities, Subparagraph D, Report of Investigation.) Investigations of transfusion-related fatalities are generally scheduled, since the facility is aware of the possibility of a follow up after the report is made to FDA. If the report of the fatality originates with any other source, i.e., media or anonymous compliant, the SA or RO conducts an unannounced survey.

The RO or the SA will assess the facility's compliance with applicable conditions and standards during the onsite review. The review may warrant investigation of departments outside the laboratory, i.e., Operating Room, Emergency Room, nursing services, medical records, to ascertain problems which may have led to the fatality. Since CLIA is specific only to laboratory testing, the SA or RO uses any preliminary information forwarded to decide whether the investigation will involve determining compliance with CLIA, the hospital (or other applicable facility) requirements, or both.

The RO or the SA will complete the applicable portions of the Form HCFA-282, Form HCFA-1557, and other applicable survey forms such as the Form HCFA-1537. A sample of the Form HCFA-282 and the corresponding instructions on how to complete it are found in Exhibit 123. The Form HCFA-2567 is prepared to document deficiencies identified during the onsite review. The RO will review and approve the HCFA-2567 before if is provided to the facility.

The report of the investigation, including all survey forms and completed PoCs is reviewed by the RO. If the RO agrees with the SA's recommendations, the RO forwards the report to the facility along with a copy to CO. CO expects a copy of the report, survey forms, and completed PoCs within 60 days of the investigation. CO forwards the report to FDA, as applicable. The RO determines what, if any, follow-up action is necessary and forwards the results of the follow-up to CO as it becomes available.

A. Transfusion Investigation in an Accredited Facility.--Consistent with other procedures involving accredited facilities, if deficiencies are found that pose an immediate jeopardy, and the SA performed the survey, the SA prepares and submits a Form HCFA-2567 to the RO for immediate action and possible sanctions within 2 days following the finding.

If deficiencies do not pose an immediate jeopardy, and the SA performs the survey, the SA prepares a Form HCFA-2567 and sends it to the facility within 10 days.

If the RO determines that the facility is out of compliance with one or more conditions, but these deficiencies do not pose an immediate jeopardy, the SA or RO notifies the facility that it is out of compliance and will be placed under the RO monitoring jurisdiction. The SA or RO forwards a copy of this notification to the appropriate representative of the facility's accreditation organization(s). The facility continues to be accredited by its accreditation organization(s). However, it is subject to the same requirements, survey, and enforcement procedures applied to nonaccredited facilities found out of compliance following a survey. The facility is monitored until it reaches Condition-level compliance or its certificate of accreditation is revoked.

If the RO determines that the accredited facility is in Condition-level compliance with all applicable HCFA requirements, the RO notifies the facility and forwards a copy of the notification to the SA and to the appropriate representative of the accreditation organization(s). For deficiencies below the Condition-level, the facility may choose to submit a PoC or not, however, any known information about the facility's efforts to correct the deficiencies should be included in the report. The notification letter advises that the accreditation organization may contact the facility about the correction of any deficiencies turned over to them from the RO.

Since CLIA is a user-funded program, the facility is responsible for payment of the fee associated with the laboratory portion of the survey, as applicable, if it is determined that the fatality was related to the laboratory's noncompliance with CLIA. (No fee is charged to the laboratory if the complaint is not substantiated.)

CLIA's jurisdiction does not go beyond laboratory testing as defined in the regulations. Thus, if it is determined that noncompliance is related to deficiencies found outside the laboratory, e.g., in the hospital or skilled nursing facility nursing services, the operating room, or emergency room, the cost incurred for the investigation is covered by the State Medicare/Medicaid Certification Inspection Budget. See Appendix C, for further information on investigation of transfusion-related fatalities.

6042. PROFICIENCY TESTING (PT)

Regulations at 42 CFR 493.801(a)(2)(i) require laboratories which have not been granted a certificate of waiver to designate annually the approved programs to be used for each specialty, subspecialty, and analyte or test to determine compliance with 42 CFR Part 493 Subpart H. This also applies to cytology PT for laboratories that are enrolled in a HCFA-approved cytology PT program. If a laboratory fails to successfully participate in PT, as defined in 42 CFR Part 493, Subpart H, the RO will take the necessary adverse actions as described in 42 CFR Part 493.

Approval and monitoring of PT programs is HCFA's CO CLIA Component's responsibility. Input that the RO/SA has collected that is based on its field experience with the laboratories and the approved PT programs will be reported to the CO CLIA Component on an ongoing basis. PT programs are to apply to the HCFA CO CLIA Component annually for approval or reapproval.

6044. ENROLLMENT INFORMATION

Annually, HCFA-approved PT programs electronically update the CLIA database with laboratories that have enrolled in HCFA-approved PT programs for specific specialties, subspecialties and analytes. HCFA-approved PT programs also update the data system on a periodic basis to reflect the addition of new laboratories. The SA (and RO for Federal jurisdictional laboratories) will verify that the laboratory is appropriately enrolled in PT.

6046. PT EXCLUDING CYTOLOGY FOR NON-ACCREDITED AND NON-CLIA EXEMPT LABORATORIES

42 CFR 493.801(a)(i) requires laboratories performing moderate and/or high complexity tests to enroll in one or more HCFA approved PT programs for each specialty, subspecialty, analyte, or test listed in 42 CFR 493, Subpart I. The laboratory must designate a specific survey (as well as PT

program) for each specialty, subspecialty, analyte, or test for regulatory purposes, so that only one score is considered for that area per testing event. The specialty, subspecialty, analyte or tests for PT are listed in 42 CFR 493.903 through 493.959. If a laboratory fails to enroll and/or appropriately test PT samples, the RO may impose any of the sanctions described in 42 CFR 493, Subpart R.

6048. NONCOMPLIANCE WITH PT ENROLLMENT AND TESTING REQUIREMENTS

PT Enrollment and Testing Requirements--In addition to successfully performing PT, a laboratory must also meet the CLIA enrollment and testing of samples condition. (See 42 CFR 493.801.) Noncompliance with this condition, which governs both enrollment and PT sample testing, may be identified during a survey.

The SA adhering to the timeframes and guidelines in Appendix C, reviews all documentation and, if called for, initiates the appropriate enforcement action(s), which are sent with recommendations to the RO. If a laboratory does not enroll in a PT program, the technical assistance and training sanction cannot be imposed if noncompliance with the PT condition is found.

6050. MONITORING PT/SCORES

The SA will obtain a report of each laboratory's PT scores from the CLIA PT monitoring system and monitor eachlaboratory's PT performance on a regular, periodic basis and prior to performing the survey. The SA (and RO for Federal jurisdictional laboratories) identifies a laboratory's noncompliance with the PT requirements for successful participation throug periodic monitoring of the OSCAR PT data system

The SA will recommend sanctions or enforcement actions, as necessary, for failure to meet PT requirements after verification of PT results from te PT organization or laboratory. (See §6268) The RO's primary role is to decide upon and implement enforcement actions following notification of noncompliance by the SA.

6052. PT REPORTS AVAILABLE TO THE SA/RO

The HCFA PT monitoring system produces the following reports:

- Listing of laboratories with unsuccessful participation/unsatisfactory performance;
- Listing of corrected scores;
- PT Organization names and addresses;
- PT organization enrollment;
- PT duplicate enrollment;
- Laboratories excused for failure to participate;
- Individual laboratory profiles; and
- Approved PT Provider Profile;

To obtain directions on how to use the PT Monitoring system, consult the OSCAR Report User's Guide or the CO OSCAR coordinator.

6054. UNSUCCESSFUL PERFORMANCE IN PROFICIENCY TESTING

If a laboratory has a report of unsuccessful performance in PT, the SA follows the procedures in §6058.

Unsuccessful participation in PT means any of the following:

- Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events;

- Unsatisfactory overall testing event scores for two consecutive, or two out of three testing events for the same specialty or subspecialty;

- An unsatisfactory testing event score for those subspecialties not graded by analyte (i.e., bacteriology, mycobacteriology, virology, parasitology, mycology, unexpected antibody detection, or compatibility testing) for the same subspecialty for two consecutive, or two out of three testing events; or

- The laboratory fails to meet the gynecologic cytology requirements at 42 CFR Part 493.855.

6056. EXCUSED CORRECTION SCORES FOR PROFICIENCY TESTING

If a laboratory has received a score of 0% due to failure to participate in a testing event for a specialty, subspecialty, analyte, or test it may request to be excused only if:

- Patient testing for that specialty or subspecialty, analyte, or test was suspended during the timeframe allotted for testing and reporting of PT results;

- The laboratory notifies RO/SA and the PT program within the timeframe for submitting PT results of the suspension of patient testing for that specialty, subspecialty, analyte, or test and of the circumstances that led to failure to perform testing on the PT samples; and

- The laboratory participated in the previous two testing events for the specialty, subspecialty.

The PT program indicates through the PT data system (i.e., excused nonparticipation report) that a laboratory has requested an excuse for failure to participate in the testing event for the specialty or subspecialty, analyte, or test. The SA will make the determination to accept or reject the request for an excused correction.

6058. UNSUCCESSFUL PARTICIPATION IN PT

Unsuccessful PT performance under CLIA is defined as unsatisfactory performance in two consecutive or two out of three events for an specialty, subspecialty, analyte, or test and requires surveyor follow-up action. The SA (and RO for Federal jurisdictional laboratories) initially identifies a laboratory's noncompliance with the PT requirements through monitoring the OSCAR PT data system report on unsuccessful participation and onsite survey for enrollment and testing.

Educational Focus.--An educational focus is recommended for initial unsuccessful PT performance to provide the laboratory an incentive to achieve successful performance and to correct all associated problems without the threat of significant sanctions. SA follow-up action for initial unsuccessful PT performance should consist of:

- Obtaining the individual results for each unsatisfactory event that contributed to the laboratory's unsuccessful performance from the laboratory or the PT provider; and

- Reviewing the PT performance reports and determining if the unsatisfactory results truly represent the laboratory's failure to perform and report the test satisfactorily. For example, clerical errors and delays in reporting still constitute failure. However, an instrument failure, PT provider data input error, or back order of reagents may not be within the laboratory's control. Careful reviews will provide a fair evaluation to the laboratory and insight into the reason for the PT failure. Problems regarding PT specimens such as matrix effect, scoring, and proper enrollment are to be handled between the laboratory and the PT provider.

Where there's a first occurrence of unsuccessful performance in a specialty or subspecialty, the SA recommends to the RO that the laboratory seeks technical assistance and/or education that is related to the specific problem. No onsite survey is required to initiate this action. When a SA determines that a laboratory has performed unsuccessfully, technical assistance and/or education may be appropriate, provided the RO agrees. An acceptable plan of remedial action should be obtained and documentation of the determinations and follow-up maintained.

SA follow-up is necessary to verify that the laboratory has obtained the recommended assistance and/or education, has corrected the problem promptly, and has documented its actions appropriately.

More stringent enforcement actions should be initiated, if:

- There is immediate jeopardy to patient health and safety;

- The laboratory refuses to correct the problem; or

- The laboratory has a history of condition level deficiencies.

Using the guidelines in §§6262 - 6294, initiate the appropriate enforcement actions. (See Exhibit 240.)

6060. REINSTATEMENT AFTER FAILURE TO SUCCESSFULLY PARTICIPATE IN PROFICIENCY TESTING

The laboratory must meet the requirements for reinstatement if:

- The laboratory's certificate has been limited or suspended, Medicare/Medicaid approval has been cancelled, or Medicare/Medicaid payments have been suspended for unsuccessful participation in PT for a specialty, subspecialty, analyte or test; or

- The laboratory has voluntarily withdrawn its CLIA certification due to a failure in that area.

Reinstatement requires sustained satisfactory performance on two consecutive PT events in the specialty, subspecialty, analyte or test which the laboratory previously failed. However, in no case may a laboratory that has had its certificate suspended, limited, or revoked because of unsuccessful participation in PT be reinstated in less than six (6) months following suspension, cancellation, limitation. The laboratory must make application to HCFA to have the specialty, subspecialty, analyte or test recertified. A revised application and certificate are necessary during the period of suspension or limitation. The laboratory must pay a fee to cover the cost of issuing the revised certificate. The RO may make a final determination whether reinstatement requirements are met. (See §6268).

6062. ONSITE OBSERVATION OF PROFICIENCY TESTING

RO/SA Surveyors may elect to observe PT performance onsite as part of the survey process or because of failure in PT by the CLIA laboratory.

The Survey Process and Related Activities

6100. THE SURVEY PROCESS--EMPHASIS, COMPONENTS AND APPLICABILITY

Survey protocols and Interpretive Guidelines provide guidance to personnel conducting surveys of laboratories. These documents are established pursuant to pertinent sections of the Social Security and Public Health Service Acts and regulations at 42 CFR Part 493. The documents serve to clarify or explain the intent of the regulations and are to be used by all surveyors assessing compliance with Federal requirements.

The outcome-oriented survey process places emphasis upon performance or outcome measurements to ensure accurate and reliable test results and other related activities. The purpose of the protocols and guidelines is to provide suggestions, interpretations, and other tools to use in preparing for and conducting the survey and for analyzing and evaluating survey findings. The use of Quality Assurance as a tool may assist with determining the laboratory's compliance with the requirements of the appropriate CLIA subparts (See Appendix C).

A survey of laboratory services includes, but is not limited to, identifying the various sources of information during the various stages of the survey process. For example, pre-survey preparation includes reviewing the laboratory's file, personnel information, services offered, proficiency testing information and compliance history.

The same survey protocol is used by both the SA and RO.

6102. SCHEDULING SURVEYS

When scheduling surveys use the following priorities:

- Complaint surveys indicating possible immediate jeopardy;
- Laboratories with other complaint investigations pending;
- History of compliance problems;
- Initial surveys of large laboratories;
- Initial surveys of small laboratories;
- Follow-up surveys; and
- Recertification surveys.

The SA or RO considers the geographic proximity of laboratories in developing an efficient survey schedule.

The SA schedules validation surveys of accredited laboratories under the direction of the RO. (See §6658.)

Laboratories holding certificates of waiver or PPMP are not routinely surveyed. (See Appendix C, and CFR 493.1775 and 493.1776.)

6104. CONDUCTING UNSCHEDULED SURVEYS

A. Survey Due to Unanticipated Events.--The SA or RO conducts a survey at an earlier date than planned if there is reason to believe the laboratory is being operated in a manner that constitutes a risk to human health. Possible reasons for this would be a complaint about deteriorating standards of operations, results of an accreditation survey of an accredited laboratory, loss of laboratory accreditation, substantial changes in managerial personnel, or a significant change (e.g., from moderate to high complexity) in the type of testing performed. The decision to conduct a survey at an earlier date than originally planned depends upon whether there is a likelihood that certification status could be changed. Such surveys must be unannounce.

B. Change of Location of Laboratory.--Changes in location of a laboratory within a State do not ordinarily require a special on-site survey. The laboratory is expected to continue to uphold the standards of operation detailed in its most recent survey. An on-site survey is to be performed only when the relocation raises significant questions as to the laboratory's ability to maintain standards. In these situations, the SA considers when the last recertification survey was performed. If a recertification survey is due within the next six months, the SA advances the entire resurvey. If the recertification survey is not due, and an on-site visit is performed, the SA conducts a limited review focusing on the issues that led to question the laboratory's ability to maintain standards. The SA documents the justification for performing special on-site surveys and maintain this documentation in the laboratory's official file.

C. Change of Testing Performed by a Laboratory.--If a laboratory, other than a laboratory with a certificate of waiver, begins to perform more tests, a SA survey or resurvey may be required. (For laboratories with a certificate of waiver that want to expand services to include non-waived testing, see §6016). The regulations permit laboratories with a certificate to add services for 6 months prior to notification to HCFA, although laboratories will not be eligible for Medicare or Medicaid payments until they have made the notification and their certificate has been revised. If a regularly scheduled survey occurs during the 6-month period a laboratory has added services but has not notified HCFA, the SA surveys the added services.

6106. SURVEY POLICY

HHS or its designee may conduct announced or unannounced survey of any laboratories at any time its hours of operation to assess compliance with applicable requirement of 42 CFR Part 493.

It is HCFA's policy to give advance notice when conducting surveys to determine compliance (including the addition of specialities/subspecialities, analyte and test, and laboratory relocation). If there is any conflict with internal State policies and practices, the SA discusses it with the RO.

The complaint or revisit surveys must be conducted on an unannounced basis. Validation surveys of accredited or CLIA-exempt laboratories are typically announced. However, in cases where there is significant disparity in survey findings, the RO has the lattitude to threat such a survey as a compliant.

A. Follow-Up Surveys.--In many circumstances, a mail or telephone contact may be sufficient in lieu of an on-site revisit. In those instances where an on-site revisit is necessary, it is be conducted by the surveyor(s) who made the findings, when possible, see §6132.

B. Waived Test Performance.--In accordance with §493.1775, if it is verified that non-waived tests are being performed at a laboratory with a certificate of waiver, the laboratory is in violation of CLIA. The SA completes a Form HCFA-1539, and in Item 16 (State Survey Agency Remarks) recommend referral to OIG. The SA completes a Statement of Deficiencies and Plan of Correction, HCFA-2567, (Exhibit 7) to indicate the findings of survey and does not solicit a Plan of Correction

(PoC). The SA attaches any documentation that can be used in the adverse action process to substantiate the recommendation and submits all of the documentation to the RO. The SA refers to §6016 if the laboratory wants to add nonwaived tests.

C. Accredited Laboratories.--Laboratories accredited by an organization approved by HCFA are deemed to meet the requirements of 42 CFR Part 493. When the RO/SA receive notification from a laboratory, which was previously inspected by the RO/SA, that it has been accredited, the SA verifies the accreditation and remove the laboratory from the biennial survey schedule. If any deficiencies are still pending on this laboratory, the SA discontinues any follow-up on the deficiencies. If the pending deficiencies were serious and represented a threat to the quality and reliability of the laboratory's testing, i.e., Condition-level deficiencies, the matter is referred to the RO. A laboratory's accreditation cannot be recognized until it has corrected its Condition-level deficiencies. The SA completes a Form HCFA-1539 to report the accreditation to the RO. The SA recertifies the compliance of each accredited laboratory on a biennial schedule consistent with their accreditation interval.

Laboratories that lose their accreditation are no longer deemed to meet the requirements of 42 CFR Part 493. Upon loss of accreditation, the SA schedules a survey of the laboratory. The SA completes a Form HCFA-1539 indicating the date of the scheduled survey in Item 16 and enters it into OSCAR as soon as the loss of accreditation is verified.

D. CLIA-exempt Laboratories.--Laboratories exempt through an approved State licensure program are subject to validation surveys conducted by the RO or its designee.

6108. SURVEY RESPONSIBILITIES

The SA uses Appendix C, The Survey Procedures and Interpretive Guidelines for Laboratories for guidance in conducting the on-site survey, and entering the information concerning the results of the survey into the CLIA database if the laboratory is in compliance. In the event of a noncompliance determination, see §6134.

6110. SURVEY TEAM SIZE AND COMPOSITION

Each SA surveyor must meet the education and training qualifications in §4009. If more than one surveyor is performing the survey, all surveyors are to survey together during the same time interval. (See Appendix C)

6112. LABORATORY SELF ASSESSMENT

For those laboratories that continue to pose potential risks to public health and safety, judging from their compliance history, regular onsite inspections present the most viable course of assuring that these laboratories maintain compliance with CLIA standards. On the other hand, for those laboratories that have sustained record of maintaining compliance, the need to have a constantly recurring onsite presence is not as compelling. For those laboratories a self assessment would be used between onsite inspections.

The Alternative Quality Assessment Survey (AQAS), HCFA-667, (Exhibit 239) is the self assessment document designed to be used by Regional Offices (RO) and State Agencies (SA) in non-waived and non-accredited laboratories. The SA should reassure the laboratory that the AQAS is a reward for exceptional performance. However, no laboratory will receive the AQAS for two consecutive certification cycles.

The criteria for using the AQAS is based on past laboratory performance. If the laboratory meeting the criteria below is in receipt of the AQAS and requests that a survey onsite be performed, the SA should direct the laboratory to complete the form . The SA uses the AQAS when laboratories meet the following criteria:

o Laboratories must have been surveyed onsite during the certification period prior to being considered for receipt of the AQAS.

o Laboratories must have had zero or minor deficiencies cited during the previous certification period. The RO will determine what constitutes a minor deficiency in order to qualify a laboratory for receipt of the AQAS.

o The criteria for selecting laboratories based on enrollment and satisfactory proficiency testing (PT) will be phased in as the PT monitoring system becomes fully operational. At that time, laboratories must have participated satisfactorily, i.e., attained a minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event, in the three PT events prior to the upcoming survey. In the meantime, the SA requests that the laboratory (see exhibit xxxx, Dear Laboratory Director letter) submit a copy of its PT results for the last three PT events.

o Laboratories performing pathology, histocompatibility and cytogenetics will not be eligible for the AQAS because of the nature and complexity of the testing and the impact on health care. These areas will be surveyed on their biennial schedule. Facilities which include pathology, histocompatibility and cytogenetics could receive the AQAS for other specialty areas provided they meet the criteria.

o Laboratories with substantiated complaints will not be eligible for the AQAS.

1. Mailing the AQAS Form.--Before mailing the AQAS form to eligible laboratories, the SA makes sure that the appropriate SA telephone number and contact person is included in the cover letter (the cover letter is not part of the AQAS form). Also, the SA ensures that the SA address is written or stamped on a label for fixing to the return envelope provided in the AQAS form packet.

2. Reviewing the Completed Form.--The purpose of the AQAS is to reward good performing laboratories, provide an educational tool for laboratories to use in preparation for the next CLIA survey onsite, and finally to be used as a mechanism to recertify laboratories. The form is designed to be consistent with current policy for the survey process onsite which focuses on a quality assurance approach for evaluating laboratories for compliance with CLIA. This approach reflects the quality assurance requirements of the CLIA regulations which require laboratories to develop, monitor, and evaluate the effectiveness of their policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff.

Demographic, personnel and test information submitted on the AQAS form should be used by the SA to update the current CLIA database information. The RO will determine whether any changes in the laboratory's personnel or type, volume and location of testing since the previous survey constitutes the need to perform a survey onsite. No question specifically flags an automatic survey onsite.

Questions should be answered by the laboratory director or appropriate designee and the form signed by the laboratory director. Along with the completed form, laboratories must submit documentation solicited by certain questions. The AQAS form directs the laboratory and reviewer to ensure that appropriate copies of documentation are submitted to the SA agency. Appendix A of the AQAS form provides a summary of those tests that a laboratory performs that are required to be enrolled in PT. Appendix B of the AQAS provides a summary of test counting policies to assist the laboratory in answering questions about test volume.

In the event that a laboratory communicates deficient practice via the AQAS, the decision to perform an onsite survey based on the completed form and supplemental documentation is left to the RO in consultation with the SA. If the AQAS is acceptable, the SA notifies the laboratory in writing of its recertification status.

3. Data Management.--The SA enters the date the AQAS form is mailed to the facility. Because the Law requires issuance of certificates every 2 years, entrance of a basic certification kit is required for AQAS (See Appendix C for the applicable HCFA forms).

Where a prompt appears in ODIE for the AQAS form, the SA enter YES. Certificates of compliance for the next 2-year certification period will be issued after appropriate review of the AQAS form and documentation, payment of applicable fees, and data entry into ODIE. The following examples provide instructions for kits involving the AQAS form where:

a. AQAS responses indicate continued compliance:

- o Note administrative time on Form HCFA-670
- o The SA enters basics certification kit with the AQAS information

b. AQAS data indicates that a survey onsite is needed:

- o AQAS becomes part of the pre-survey activity/history;
- o The SA conducts survey onsite and enters information in usual manner;
- o Survey time is entered on Form HCFA-670 and may be billed as follow-up.

6114. AQAS VERIFICATIONS AND SUMMARIES

AQAS Verification Surveys.--Each RO determines the number of laboratories in its jurisdiction that will receive the AQAS form based on the criteria described at §6112. An approximate percentage of the total number of laboratories that receive Form HCFA-667, as a self assessment, will be selected for a survey onsite for verification purposes (see budget call letter). AQAS verification surveys are conducted onsite after form HCFA-667 has been returned to the SA to substantiate the laboratory's responses on the form. Using the completed AQAS form as guide, the verification process should focus on verifying the laboratory's responses. If deficiencies are noted the SA issues a deficiency report Form HCFA-2567 and solicits the appropriate PoC. Verification information cannot presently be entered into the OSCAR system.

Selection of laboratories for verification is at the discretion of the RO. If the laboratories meeting the criteria for receipt of Form HCFA-667 requests a survey onsite, the RO or SA confirms that the laboratory agrees to also complete the form. Such laboratories can be considered part of the AQAS verification pool. Laboratories meeting the criteria for receipt of form HCFA-667 and that do not wish to complete the form will be removed from the AQAS pool and be surveyed onsite.

AQAS Summaries--ROs/SAs should compare the data from the AQAS (Form HCFA-667) received by those laboratories selected for verification with the onsite verification data and prepare a summary of the comparison results. The RO forwards this summary to the CO CLIA component on an annual basis. Contact CO to obtain guidance to prepare summary.

6116. LABORATORY REFUSES TO ALLOW SURVEY

Section 353(g) of the PHSA permits authorized officials to make announced or unannounced surveys of laboratories holding any type of CLIA certificate, at any time during the laboratory's normal hours of operation. If access is refused, the SA documents the identity (name and title) of the individual refusing admission and the reasons given, and submit this documentation immediately to the RO, i.e., by telephone or telecopy. In addition, regulations at 42 CFR §1001.1301 permit the OIG to exclude a laboratory from the CLIA program if it fails to grant immediate access upon reasonable request. The exclusion may be in effect up to a period equal to the sum of the length of the period during which immediate access was not granted, plus an additional 90 days. The RO will make the referral to the OIG. (See §6270.)

6118. DURING THE SURVEY

The surveyor(s) may allow or refuse to allow laboratory personnel to accompany surveyor(s) during certain phases of the survey. The surveyors must not allow managerial personnel to be present during staff interviews. The SA should exercise discretion in each case. Laboratory personnel may be helpful, answer questions, or point out certain things of concern to the surveyors. The surveyor should use such assistance if it is helpful to the survey and makes the process easier. Conversely, laboratory personnel may harass surveyor(s), argue about observed problems, and make the survey more difficult. The surveyor should not tolerate such treatment.

6120. COMPLETING THE SURVEY REPORT FORM (HCFA-1557)

The HCFA-1557 (Exhibit 12) is the vehicle for documenting general laboratory information and is designed to facilitate electronic data entry of survey findings.

A. General.--The HCFA-1557 is filled out at the time of the survey, and includes survey data that must be entered into the CLIA data system. It includes information used in preparing the HCFA-2567, Statement of Deficiencies and Plan of Correction.

B. Specific Items to Consider When Completing the Form HCFA-1557.--When completing the HCFA-1557 during the survey, surveyor should pay particular attention to the following items.

1. Personnel.--Prior to filling out the personnel section of the HCFA-1557, complete a HCFA-209, Laboratory Personnel Report (CLIA) (Exhibit 106), which requires more detailed information concerning the qualification of the laboratory's personnel. Only persons listed on a HCFA-209 are to be included in the classification totals on the Form HCFA-1557. The surveyor reviews a sample of Testing Personnel qualifications to verify the documentation on the HCFA-209.

2. Specialties/Subspecialties.--The surveyor indicates all categories where at least one test is performed in a specialty or subspecialty, and notes additions, deletions and appropriate effective dates on the form.

3. Deficiencies.--The surveyor uses the Interpretive Guidelines during the survey and notes the tag numbers relating to any deficiencies observed along with data supporting the findings on the surveyor worksheet. It is important to maintain accurate notes of observations, since the information is used to prepare a HCFA-2567.

4. Signature.--All members of the survey team are required to sign the Form HCFA-1557.

6122. CREDENTIALING OF FOREIGN TRAINED LABORATORY PERSONNEL

Personnel employed in laboratories subject to CLIA which perform tests of moderate and/or high complexity must meet specific education, training, and experience requirements. In the case of individuals who attend foreign schools, evaluations concerning the equivalency of foreign to United States education must be made by an organization which is a member of the National Association of Credential Evaluation Services, Inc. (NACES). A listing of current members of NACES is found in the Appendix C, in the guidelines section for Subpart A.

The laboratory should maintain a copy of the equivalency determination in the individual's personnel folder.

6124. PREPARATION FOR EXIT CONFERENCE

The surveyors hold a survey team meeting prior to the exit conference and come to a consensus on the scope and severity of the deficiencies and whether the number, character, or combination interfere with accurate and reliable laboratory test results. Deficiencies found in more than one Condition or standard may be cumulative and interrelated and result in general, pervasive inadequacies in determining test results.

6126. EXIT CONFERENCE

Subsequent to the pre-exit meeting held to allow team members to exchange and formulate survey findings, the team conducts an exit conference. Its purpose is to informally communicate the survey team's findings, and to provide an opportunity for the exchange of information with the laboratory. Although it is HCFA's general policy to conduct an exit conference, the surveyor should be aware of situations that would justify a refusal to conduct or continue an exit conference. For example:

- o If the laboratory is represented by counsel (all participants in the exit conference should identify themselves), the surveyor should refuse to continue the conference if the lawyer tries to turn it into an evidentiary hearing.

- o Any time the laboratory creates an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference, the surveyors should refuse to continue the exit conference.

- o If the laboratory wishes to audio tape the conference, it must tape the entire meeting and provide surveyor(s) with a copy of the tape at the conclusion of the conference. Videotaping is also permitted if it does not intimidate the surveyors or disrupt the conference, and a copy is provided at the conclusion of the conference. Use discretion in deciding whether to permit videotaping. (See §2724.)

The survey team should establish control and maintain it throughout the exit conference. The survey team presents the findings but should refrain from arguing. The surveyors should be mindful that laboratory staff are likely to react defensively to findings. The laboratory representatives have a right to disagree with survey findings and to present information to refute them and the team should be receptive to such disagreements. If the laboratory representatives present information to negate any of the survey findings, the surveyor(s) should indicate willingness to reevaluate the findings before leaving the laboratory. If deficiencies are corrected before the completion of the survey, the surveyor should acknowledge the corrections and explain how this situation will be documented. (See §6130.) The following guidelines are helpful in performing an exit conference:

A. Introductory Remarks.--A surveyor should introduce other members of the survey team and restate the purpose of the survey. A surveyor expresses the team's appreciation for anything the staff has done to facilitate the survey and explains that the exit conference is an informal meeting to discuss preliminary survey findings and thereby to assist the laboratory in developing an acceptable PoC. A team member should indicate that the official findings are presented in writing on the Form HCFA-2567 and will be forwarded to the laboratory within 10 calendar days. The laboratory must also be informed they are to return the POC in 10 calender days.

B. Ground Rules.--The surveyor(s) will explain how the exit conference will be conducted and how the team's findings will be presented, i.e., each surveyor will present his/her own findings. A surveyor should inform the laboratory that where there are disagreements between the team and the laboratory over the findings they will have the opportunity to submit additional evidence after the conference.

C. Presentation of Findings.--In presenting findings, the surveyors cites problems that clearly violate regulatory requirements. Provide an explanation to the laboratory concerning the deficiency in specific terms (no data tags or regulation citations) to allow the laboratory to understand why the requirement is not met. Frequently, the explanation will imply the action needed to correct the problem. There may be several possible causes for the deficiency or deficiencies and it is not surveyor(s) responsibility to delve into the laboratory's policies and procedures to determine the root cause of the deficiency or to sift through various alternatives to suggest an acceptable remedy. For example, if a laboratory was cited for maintaining incomplete patient specimen records, the surveyor specifies what is missing, not why it is missing or what process is best for ensuring that the records are complete in the future. If asked for the regulatory basis, the surveyor provides it. Surveyor should stick to the facts and treat requirements as equally as possible.

D. Closure.--When the exit conference is completed, the surveyor explains the certification process to the laboratory and informs them that a formal statement of deficiencies will be provided within 10 days. The surveyor explains the due date for submitting a PoC and how the rest of the certification process works.

If immediate jeopardy situation has been identified, the survyor explains the significance of that finding and the need for immediate corrective action to remove the jeopardy. In this or any other instance where adverse action is anticipated, the surveyor explains the implications, making it clear that only compliance will stop the action. The surveyor advises the laboratory that a revisit to verify correction of deficiencies occurs only when the laboratory makes a credible allegation of compliance. If the laboratory does not notify RO/SA with a credible allegation of compliance, no revisit will be made and the adverse action process will continue.

In an initial survey, the surveyor tells the laboratory to expect notification from HCFA of their initial approval (issuance of a certificate) or determination of noncompliance. For subsequent biennial surveys, the surveyor explains that HCFA issues an updated certificate reflecting any changes in approved services.

6128. CERTIFICATION ACTIONS PERFORMED AFTER SURVEY

The post-survey certification processes are summarized as follows:

- If extensive documentation is required for a finding of immediate jeopardy, the surveyor should gather the necessary additional evidence.

- The surveyor completes survey documents. (see Appendix C); and

o The Form HCFA-2567 is sent to the laboratory requesting a PoC, if appropriate. (See Exhibit 111.) A PoC is required for all deficiencies, except in cases of immediate jeopardy where limitations or suspension of the certificate may be imposed prior to an opportunity for a hearing.

The SA should be prepared to modify the revisit schedule for unexpected changes or requested changes in the laboratory's status, or for subsequent changes in compliance status.

6130. STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION, Form HCFA-2567

The Form HCFA-2567 serves several important functions, as follows:

o Documents that specific deficiencies were cited. If there are no citations, the surveyors indicates this in the left-hand column of the HCFA-2567;

o Documents the laboratory's receipt of the deficiency notice;

o Discloses to the public the laboratory's deficiencies and what is being done to remedy them;

o Provides an opportunity for the laboratory to refute survey findings and to furnish documentation that requirements are met; and

o Documents the laboratory's plans and time frames for correcting the deficiencies.

The SA mails the laboratory a copy within 10 calendar days of completing the survey. If there are citations, the SA allows the laboratory 10 calendar days to complete and return the PoC. If immediate jeopardy is identified, the SA follows the time frames in §6282.

A. Statement of Deficiencies.--The Form HCFA-2567 can be generated using the computer program ASPEN or the multi-page form. Direct references to regulations are shown with a corresponding D, data tag number. In the summary statement column at the appropriate D tag number, the surveyor includes the regulatory citation along with the description of the laboratory's deficient practices. The surveyor should refer to the Principles of Documentation manual for preparing a defensible citation.

Positive findings noted on the Form HCFA-1557 are not to appear on the Form HCFA-2567.

In cases where an adverse action is a possibility, the SA provides thorough and comprehensive documentation to support the survey findings and certification decisions to sustain the action in the event of a hearing or judicial review. The SA uses all available sources of information to assist with completing the Form HCFA-2567.

B. Plan of Correction (PoC).--The laboratory enters its planned action to correct the deficiency and the expected completion date opposite the appropriate data tag on HCFA-2567. Alternatively, the laboratory may enter its disagreement with a finding and may furnish documentation that requirements are met. If a deficiency has been corrected since the survey, the laboratory should indicate this on the form along with the date of correction. The plan must be specific and time frames realistic, stating exactly how the deficiency will be corrected or how it was corrected. It must be signed by the laboratory director or other authorized official and dated.

If the laboratory director requests additional time to develop the plan, the SA explains that a preliminary PoC must be submitted within 10 days, as precisely as present information permits, and that it may be followed with a more specific plan as early as possible. The Form HCFA-2567 is

disclosable to the public within 90 days of completing the survey, but not to exceed 30 days following receipt of the report by the RO. Also, the SA advises that a future contact or revisit to verify correction of deficiencies will occur only when the laboratory makes a credible allegation that it has corrected its deficiencies.

After completing the PoC, if the Form HCFA-2567 was generated using ASPEN, the SA instructs the laboratory to retain a copy and return the original to RO/SA within 10 days of receipt. If the multi-page HCFA-2567 is used, the SA instructs the laboratory to retain the fifth copy and return the rest to RO/SA within 10 days of receipt. If the response attempts to refute a citation, the SA contacts the laboratory to resolve the disagreement. If not resolved, the laboratory should put its protest in writing in a form suitable for disclosure, but must still provide its plan and time frame for correction.

If the laboratory corrects a cited deficiency before the completion of the survey, the SA documents the deficiency on the Form HCFA-2567 and explains to the laboratory director that when the laboratory receives the Form HCFA-2567, it is to indicate the correction as of that date.

It is not acceptable, under any circumstances, for a laboratory to allude in any way to another laboratory or to malign an individual on a publicly disclosable Form HCFA-2567. Therefore, the SA removes statements of this nature and obtains an amended PoC.

C. Review of Plan of Correction by State Agency.--The SA reviews the laboratory's PoC for appropriateness, legibility, completeness, and timeliness. If not properly completed or there is a question about the PoC, and the SA contacts the laboratory representative to obtain clarification or appropriate modification of the plan. The SA retains a copy of the HCFA-2567 in the file and associate additional copies with the certification packet.

D. Modification of Plans of Correction.--Evidence of correction or a modified PoC may be submitted to RO/SA by the laboratory at any time. The SA retains a copy of the material in the certification file and forwards the original to the RO if an adverse action is pending.

6132. FOLLOW-UP ON PoCs

A. Post-Survey Revisit.--The SA follows-up on all citations cited in the PoC only after the laboratory makes a credible allegation of compliance. In some cases, the citations may be of such a nature that an electronic transmission, mail or telephone contact may suffice in lieu of an on-site visit, e.g., the laboratory agreed to amend its written policies. An electronic transmission, mail or telephone contact is acceptable as long as there have been no reason to question the validity of the reported corrections. If documentary or on-site verification is warranted, the SA obtains appropriate verification before reporting a citation as corrected and completes a Post-Certification Revisit Report, Form HCFA-2567B (Exhibit 8).

B. Post-Survey Revisit Report, Form HCFA-2567B.--At the time of the follow-up visit or when corrections are verifiable by electronic transmission, telephone contact, or mail, the SA completes a HCFA-2567B for the deficiencies previously reported which have been corrected. The SA enters:

1. Laboratory identification information;

2. Date of the revisit or date of verification;

3. Prefix tag;

4. Corresponding regulatory reference cited on the original Form HCFA-2567; and

5. Date the correction was completed.

If possible, the review is to be conducted by a member of the survey team which made the findings. The SA has the completed form initialed by the reviewing official, retains the fourth copy for the file, and mails a copy to the laboratory. The SA enters it into the CLIA data system and if an adverse action is in progress, forward the remaining copy to the RO.

If, at the time of the revisit, some deficiencies have not been corrected, the SA completes another Form HCFA-2567 summarizing the deficiencies not corrected by using the appropriate data prefix tag number. The SA must ask the laboratory to provide a revised POC with a new completion date. The SA annotates under the heading Statement of Deficiencies and Plan of Correction, "Summary of Deficiencies Not Corrected on a Follow-Up Visit" and shows the date of the revisit beneath the date of the survey.

The SA associates a copy of the revised Form HCFA-2567 with the Form HCFA-2567B and retains it for the laboratory file. The SA sends a copy to the laboratory and inputs the data to the CLIA data system. If failure to correct deficiencies results in the laboratory no longer being in compliance, the SA documents the case for enforcement action.

C. Notifying Responsible Parties of Continuing Deficiencies.--The SA communicates directly with the director on a routine basis. The SA notifies the owner, governing body, or other responsible parties if a director has been ineffective in correcting deficiencies and advises the director of such actions.

6134. EVALUATION OF COMPLIANCE

The CLIA requirements establish a single set of conditions and standards for all laboratories. CLIA certification satisfies program eligibility requirements for participation under Medicare and Medicaid.

During the laboratory survey, the SA compiles all information required to determine compliance, and completes all official reports of survey findings. Survey findings under CLIA requirements are determinations made by surveyors. When the survey reports and a form HCFA-1539 are entered into the CLIA data base, an official determination of CLIA compliance is made. There are three types of compliance for any laboratory:

A. Compliance with all CLIA Conditions with No Deficiencies Identified.--This indicates that there are no deficiencies identified. The laboratory is issued the appropriate CLIA certificate and is eligible to participate in the Medicare and Medicaid programs.

B. Compliance Based on an Acceptable PoC.--Compliance based on an acceptable PoC reflects the findings that all applicable Conditions are met, but there are deficiencies below the Condition level for which the laboratory has submitted an acceptable PoC. The surveyor is certifying that the laboratory is able to furnish test results without hazard to the health and safety of patients. Laboratories having deficiencies must correct them within a acceptable time frame (no later than 12 months). Compliance based on an acceptable PoC varies with the level, nature and seriousness of the deficiencies.

In reviewing the PoC, the SA evaluates whether or not the corrective action will result in compliance within the time frame indicated and that time frame is an acceptable amount of time. If the laboratory does not submit an acceptable POC or if it fails to correct its deficiencies, the SA/RO withdraws the laboratory's approval to receive Medicare and Medicaid payment and revoke its certificate, as appropriate. (See §6284.)

C. Noncompliance.--In situations where it is determined that a laboratory has failed to comply with one or more CLIA conditions, the SA certifies noncompliance to the RO by submitting a Form HCFA-1539 (Code Item 4 as 9-Other), and recommends a sanction action. (See §6262.) When certifying noncompliance, the SA enters the survey findings into the CLIA database and sends a hardcopy of the Form HCFA-2567 to the RO. After reviewing the HCFA-2567, the RO makes a final determination of noncompliance and enters the final determination into the CLIA data system.

6136. COMPLAINTS INVOLVING LABORATORIES

A complaint is an allegation that could result in citing noncompliance with CLIA requirements. A complaint may be substantiated or unsubstantiated as a result of investigation or survey. A substantiated complaint is one resulting in a finding of noncompliance at the time of the investigation, or a finding that noncompliance was proven to exist, but was corrected prior to the investigation. An unsubstantiated complaint is an allegation where sufficient evidence could not be found to conclude that noncompliance with CLIA requirements existed during the investigation or at the time of the alleged violation. A complaint may be received in either the SA or the RO. The receiving organization should should follow these procedures.

The SA obtains the following information for every complaint:

- Complainant's name, address and telephone number (unless complainant requests anonymity);
- Laboratory's name and address; and
- Description of problem, (e.g., personnel, places, and dates of occurrence).

A. Control.--The SA establishes a file for the complaint and logs the action in a control system. The system may be manual or automated, but must facilitate tracking and control of the complaint.

B. Acknowledgment.--If the complainant is known, the SA promptly issues written acknowledgment that the complaint is being investigated. The SA should not delay acknowledgment pending an investigation unless the investigation will take place within 3 working days. The SA must take appropriate precautions to protect the complainant's anonymity and privacy. The SA maintains a copy or record of the notification with the complaint documentation.

C. Evaluation.--The SA evaluates any complaint to determine whether it should be investigated by the SA or RO, or forwarded by the RO to the appropriate authority (e.g., OCR, OSHA, accreditation organization) for investigation or referral. The SA assesses the complaint to determine if an immediate survey is necessary. While most complaint surveys will be performed by the SA, certain complaints involving CLIA-exempt or State operated facilities are the responsibility of the RO. When the SA does not have jurisdiction, it should forward the complaint to the RO within 3 working days. If referral is not necessary, the SA considers whether or not any special notification is appropriate. (See section 6220-6224.)

If a complaint is especially significant, sensitive, or attracting broad public or media attention, the SA informs the RO immediately.

D. Scheduling Investigations.--For CLIA exempt laboratories see §§6220 - 6224 and for laboratories holding a certificate of accreditation see §§6174 - 6182. For all other laboratories, if the complaint involves possible immediate jeopardy to patient health and safety, the SA investigates within 2 working days of receipt, and focuses on the specific problem area. Otherwise, the SA follows procedures for prioritizing and investigating certification-related complaints. Laboratories with complaints pending are identified and given priority in scheduling of regular certification surveys. The SA follows existing procedures for the actual survey.

E. Conducting Investigations.--The SA investigates complaints by means of an on-site survey, by telephone by electronic communication, or by letter, or by a documentary review. Complaint investigations are unannounced.

For on-site complaint investigations, the SA performs a full or partial survey based on the allegations. If a complaint alleges generalized inappropriate laboratory practices, the SA evaluates compliance with applicable requirements or conducts a full survey, as needed. If the complaint is of a specific nature, the SA performs a survey focused on areas relevant to the complaint.

F. Conducting Investigations in a Laboratory with a Certificate of Waiver.--The RO authorizes an unannounced complaint survey of a laboratory holding a certificate of waiver only if based on a substantial allegation of noncompliance. The fact that a deficiency is not at the Condition-level does not preclude taking adverse action based on provision contained in 42CFR 493.1840. As with other laboratories, the SA investigates complaints made against laboratories with a certificate of waiver by means of an on-site survey, by telephone or letter, or by a review of documents.

The SA performs the on-site investigation based on the allegation and determines whether a laboratory is performing only waived tests and if the laboratory is following the manufacturer's instructions for performing the tests. (See Appendix C.)

G. Conducting Investigations in a Laboratory with a Certificate for PPM Procedures.--The RO authorizes an unannounced complaint survey of a laboratory holding a certificate for PPM procedures only if based on a substantial allegation of noncompliance. This survey should not differ from a complaint survey done in any other laboratory performing non-waived testing, as all requirements for moderate complexity apply except routine survey.

Substantial indication that a laboratory is performing tests that do not appear on the PPM procedures test list (e.g., through billing procedures) should prompt a complaint survey of a certificate for PPM procedures laboratory followed by either proper registration or appropriate sanctions.

H. Post Investigation Actions.--Following the investigation, the SA records any deficiencies on a HCFA-2567 and provides it to the facility using regular procedures. Subsequent actions depend on the severity and nature of the deficiencies cited and the facility's willingness or ability to correct them.

When deficiencies are identified, the SA initiates actions as follows:

1. Condition-Level Deficiencies - Immediate Jeopardy.--Certifies noncompliance and initiate procedures to recommend imposing alternative and principal sanctions.

2. Condition-Level Deficiencies - No Immediate Jeopardy Facility Provides an Acceptable Plan of Correction.--Certifies noncompliance and initiate procedures to recommend imposing alternative sanctions based on the severity and nature of the deficiencies found.

3. Lower Level Deficiencies - Facility Provides an Acceptable PoC.--Certifies compliance based upon an acceptable PoC and assembles documentation for RO review.

4. Lower Level Deficiencies - Facility Unable or Unwilling to Provide Acceptable PoC.--A facility with deficiencies may not participate without an acceptable PoC. The SA recommends sanction action to the RO.

When no deficiencies are identified, no certification action is required.

I. Resolution/Closeout.--

1. Unsubstantiated.--The SA enters the unsubstantiated complaint into the CLIA data system, and logs summary information in the control system and document the facility's certification file.

2. Substantiated.--The SA reports substantiated complaints using the Form HCFA-2567 and any appropriate supporting documentation. The SA logs summary information in the control system and files a copy of the complaint documents in the facility's certification file. The SA enters into the CLIA data system for RO action. The RO notifies the SA of any additional actions needed and provides copies of any appropriate documents. The laboratory will be charged a fee to cover the cost of the survey if noncompliance is documented.

The SA closes out all complaints with a follow-up notice to the complainant with the findings and disposition of the complaint. The SA should send this notice soon after the investigation and retains a copy with the complaint record.

The SA provides follow-up reports, as necessary, to any other appropriate parties such as the State Medicaid agency and/or initial referring agencies. The SA must be sure to protect the privacy of the complainant.

The SA inputs the investigation information into OSCAR system within 45 days of the completion of the complaint survey.

6138. RETENTION OF CLIA CERTIFICATION RECORDS

Essential data from all CLIA forms can be captured electronically in HCFA's mainframe data system, which will maintain these data for 3 years following the year in which the record is created, pursuant to Subpart R of the Federal Acquisition Regulations (incorporated by reference in Article XII.A of the §1864 agreement). The 1864 agreement and Subpart R do not preclude limiting data captured to "essential" elements. For example, the deficiency codes and correction dates from the Form HCFA-2567 are essential, but the narrative description of deficiencies or corrections are not.

Article XII.A of the §1864 agreement requires retention of survey and certification records for three years following the year in which the record is created. This provision permits retention of the records in electronic form. However, where State law requires retention of records for a longer period or in specific formats, State law is controlling.

The following sections specify record retention requirements for different compliance situations.

A. No Deficiencies Cited.--Upon completion of a survey in which no deficiencies are cited, the SA enters all applicable CLIA survey forms (See Appendix C) into the HCFA data system and discard hard copies.

B. Deficiencies Cited.--Upon completion of a survey where deficiencies are cited, the SA enters all forms into the data system as required above. In addition, the SA forwards a hardcopy of the Form HCFA-2567 to the RO when certifying noncompliance and retains the above forms in hardcopy form until all corrections specified on a PoC are completed, or if an adverse action is initiated, upon exhaustion of the CLIA/Medicare appeals process.

C. Exception.--The SA retains a hard copy of the Laboratory Personnel Report, Form HCFA-209, until update or revision at the next survey to prevent evaluation of the same personnel on two consecutive surveys as part of the survey sample of personnel.

Sample and Complaint Validation Surveys of Accredited Laboratories

6150. BACKGROUND--HCFA APPROVAL AND WITHDRAWAL OF APPROVAL OF ACCREDITATION ORGANIZATIONS

Section 353(e) of the PHSA permits the Secretary to approve private nonprofit accreditation organizations and thereby determine that laboratories accredited by the approved accreditation organization are deemed to meet CLIA requirements. To obtain a certificate of accreditation, a laboratory must meet the standards of an approved accreditation organization and authorize the organization to submit to HCFA the accreditation survey records or other information HCFA requires. When HCFA approves an accreditation organization, a notice is published in the Federal Register stating the name of the organization the specialities and subspecialities for which it is approved, and the basis for the approval of that accreditation organization. If it is later determined that the accreditation organization no longer meets the applicable requirements set forth in 42 CFR Part 493, Subpart E of the regulations, HCFA will publish a notice in the Federal Register containing a justification of the basis for removing deeming authority from an accreditation organization. An accreditation organization may be approved for no longer than 6 years and then reapply for deemed status. The SA or the RO are to conduct sample and complaint validation surveys to ensure that requirements equal to or more stringent than the CLIA requirements are being met by accredited laboratories. The validation survey covers all CLIA conditions in the specialties and subspecialties for which the accreditation organization is approved. HCFA periodically evaluates the results of validation surveys. As part of the validation review process, HCFA may conduct on-site visits at the accreditation organization's headquarters to verify administrative integrity.

6152. ACCREDITATION VALIDATION SURVEYS - CITATIONS AND GENERAL DESCRIPTION

The statutory basis for validation surveys of accredited laboratories is found in §353(e)(2)(D) of the PHSA. Regulations authorizing such surveys are found at 42 CFR Part 493, Subpart E, Accreditation by a Private, Nonprofit Accreditation Organization or Exemption under Approved State Laboratory Programs. 42 CFR Part 493.507(a)(1) provides that validation surveys will be conducted on a representative sample basis or in response to substantial allegations of noncompliance.

An accredited laboratory means that a laboratory has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by HCFA. An accredited laboratory will be deemed to meet CLIA conditions if the laboratory authorizes the accreditation organization to submit to the SA, or another HCFA agent, records or other information that HCFA requires, and permits surveys as required by CLIA regulations. A laboratory deemed to meet CLIA requirements must successfully participate in a HCFA approved PT program.

6154. OBJECTIVE OF VALIDATION SURVEYS OF ACCREDITED LABORATORIES

The Validation program is designed to evaluate the premise that a laboratory which receives accreditation is in fact meeting CLIA requirements. The findings of laboratory validation surveys are used to develop a reasonable estimate of an accreditation organization's performance and to assess the ongoing acceptability of accreditation as an alternative to routine survey and certification activities. Validation surveys are to be conducted with established procedures for certification surveys of nonaccredited laboratories to assure a fair basis for comparing the effectiveness of laboratory accreditation programs.

6156. SELECTION OF SAMPLE FOR VALIDATION SURVEYS OF ACCREDITED LABORATORIES

The number of validation surveys performed each year is approximately 5% of accredited laboratories due for surveys that year. Monies are allocated proportionately in the SA budgets for this purpose.

CO will obtain each accrediting organization's schedule of planned surveys on a periodic basis and forward them to the ROs, sometimes with additional direction. Each RO will use the schedule to select those laboratories to be validated by the SAs based on the following criteria:

A. Selecting from small, medium and large laboratories;

B. Selecting laboratories that are geographically dispersed;

C. Avoiding the over-selection of laboratories with common ownership, i.e., common owners; and

D. Laboratories that encompass, in whole or in part (to the extent possible), the entire range of specialty and subspecialty testing.

In some cases, CO may provide direction for the selection of laboratories to avoid the under or over selection of certain accredited laboratories. It is possible that, not all HCFA ROs will be overseeing validation survey activities for all accrediting organizations in a given year, due to the small universe of laboratories accredited by some organizations.

6158. PREPARING FOR VALIDATION SURVEYS OF ACCREDITED LABORATORIES

A validation survey is initiated when the RO sends the SA a Request for Validation Survey of Laboratory, Form HCFA-2802A (Exhibit 242) with Item 4 checked to indicate that the survey is a validation survey of an accredited laboratory. The SA schedules the survey no later than 60 days after the accreditation survey.

Validation surveys are typically announced (See §6106). The SA must ascertain the hours when testing is conducted in the laboratory to assure that the survey is conducted at a time when the laboratory is normally functioning.

The SA will assign laboratory surveyors who normally conduct surveys of nonaccredited laboratories. The SA completes the survey in approximately the same time frame required for a nonaccredited laboratory of similar size and complexity. All team members are required to inspect a laboratory concurrently, even if this is not usual SA procedure.

Hospital validation surveys are coordinated through the CO component responsible for Hospitals. When the RO is requested to perform a validation survey in a particular hospital, this should be communicated to the RO CLIA coordinators. Every effort should be made to coordinate the hospital validation survey with the laboratory validation survey to conduct them concurrently.

At the discretion of the RO, validation surveys may be performed concurrently with the accrediting organization's survey. The RO establishes appropriate policies concerning concurrent validation surveys.

At the discretion of the RO, the RO may plan to accompany the SA on validation survey in order to assist in the survey or to monitor consistency in the validation survey process.

6160. AUTHORIZATION FOR RELEASE OF ACCREDITATION SURVEY

The Laboratory Authorization Form (Exhibit 108) is included in the CLIA application. If the laboratory representative refuses to authorize the release of accreditation survey findings the SA will inform the laboratory that failure to do so is sufficient basis for transfer of survey responsibility to it or to HCFA, and the laboratory's certificate of accreditation may be subject to suspension, revocation or limitation under the provisions of 42 CFR Part 493.507(c).

6162. ACCREDITED LABORATORY'S REFUSAL TO PERMIT A VALIDATION SURVEY

If a laboratory selected for survey fails to comply with the validation survey procedures, the RO notifies the laboratory, by letter, that it will be subject to full review and survey, and that the laboratory is subject to suspension and revocation of its CLIA certificate of accreditation. The RO will send a copy of the letter to the accreditation organization, SA and CO. An accredited laboratory will be considered deemed to meet the CLIA Conditions when:

o It withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation survey, PT results, or notification of any adverse actions resulting from PT failure;

o It withdraws any prior refusal to allow a validation survey; and

o HCFA finds that the laboratory meets all the CLIA conditions.

6164. CONDUCTING VALIDATION SURVEYS OF ACCREDITED LABORATORIES

The SA conducts the inspection in accordance with the survey protocol discussed in §6150, along with the usual objectivity so that there is a fair basis for evaluating the effectiveness of the accreditation process. To permit an independent compliance decision a copy of the accreditation organization's findings will not be provided to the SA prior to the completion of the validation survey.

The SA is responsible for:

o Upon receipt of Form HCFA-2802A (Exhibit 107) from the RO, scheduling the validation survey(s) to take place no later than 60 days after the accrediting organization's survey;

o Assignment of surveyors on rotating basis to perform the validation survey, as available;

o Performance of the validation survey using the same survey process and the same objectivity as in a survey of a nonaccredited laboratory;

o Completion of the appropriate paperwork as would be necessary for any routine survey of a nonaccredited laboratory, as applicable, and forwarding the paperwork to the RO; (See Appendix C)

o Performance of an exit conference which outlines the survey findings and informs the laboratory of any follow-up actions or correspondence.

NOTE:

If, during the course of a validation survey in an accredited laboratory, the laboratory is found to be performing more or less tests and/or specialties than reflected in the CLIA data base, i.e., the laboratory is in a higher or lower schedule, the discrepancy must be corrected. (See Appendix C)

6166. RESULTS OF VALIDATION SURVEYS OF ACCREDITED LABORATORIES

A. Condition-Level Deficiencies with Immediate Jeopardy.--

1. The SA.--

o Informs the laboratory of its noncompliance status. The SA explains to the laboratory that it will recommend to the RO that the laboratory no longer meets the CLIA condition-level

requirements by virtue of accreditation. The laboratory is subject to principal and/or alternative sanctions by the RO;

o Prepares a Statement of Deficiencies, Form HCFA-2567, and/or clearly documents the nature of the jeopardy and immediately (within 2 days) notifies the RO with the recommended action. The SA does not leave the Form HCFA-2567 with the laboratory at the time of the exit conference.

o Forwards the validation survey certification package to the RO.

2. The RO.--

o Receives the SA recommendations and determines the appropriate actions to be taken, according to the policies for actions to take when immediate jeopardy exits. To encourage immediate action by the laboratory to remove the jeopardy situation, the RO may initiate immediate action to suspend or limit the laboratory's certificate of accreditation or seek a temporary injunction or restraining order against the continuation of that activity by the laboratory; and

o Notifies the laboratory of the immediate jeopardy situation by overnight mail or facsimile (followed up by mail) and of the actions being initiated (Exhibit 237). A copy of this communication is sent to the SA, CO, and the applicable accrediting organization. (Call CLIA component at CO for current contact and address)

B. Condition-Level Deficiencies with No Immediate Jeopardy.--

1. The SA.--

o At the exit conference, informs the laboratory of its condition-level noncompliance status. The SA explains to the laboratory that it will recommend to the RO that the laboratory no longer meets the CLIA condition-level requirements for the applicable specialty and/or subspecialties by virtue of accreditation.

o Explains that the Form HCFA-2567 will be sent to the laboratory in approximately 10 days from the RO. A plan of correction is due (usually to the SA) within 10 days of receiving the HCFA-2567.

o Prepares a Form HCFA-2567 and forwards the validation survey certification package to the RO. (See § 6635 Forwarding Completed Validation Survey information to CO.)

2. The RO.--

o Receives the SA recommendations and determines the appropriate actions to take, according to the policies for actions to take when condition-level noncompliance exists.

o Notifies the laboratory within approximately 10 days of the validation survey date that it is out of condition-level compliance.

o Requests a plan of correction, and informs the laboratory that the SA will follow-up with the laboratory to determine whether condition-level compliance has been achieved (Exhibit 238).

3. The SA.--

o Receives the laboratory's plan of correction and determines whether it is acceptable. If not, the SA informs the laboratory that its plan of correction is not acceptable and that it must resubmit one that is acceptable.

o Forwards an acceptable plan of correction to the RO.

o Monitors the laboratory at the direction of the RO and ceases monitoring activities at the direction of the RO.

4. The RO.--

o Verifies the acceptable plan of correction and notifies the laboratory of its acceptance (Exhibit 223);

o Notifies the laboratory when compliance has been achieved (Exhibit 224) and ceases directive for SA follow-up;

o Copies all correspondence with the laboratory to the SA and accrediting organization.

o Copies the Form HCFA-2567 and plan of correction to CLIA component at CO for comparison with the accrediting organization's survey report. (See §6170 Forwarding Completed Validation survey Information to CO.)

C. Deficiencies Found Below the Cndition-Level.--

1. The SA--

o At the exit conference, informs the laboratory that it is in condition-level compliance with the CLIA requirements, but that standard level deficiencies were identified.

o Explains to the laboratory that it will receive a Form HCFA-2567. The laboratory is encouraged to submit a plan of correction since the HCFA-2567 is subject to Federal disclosure rules and can be publicly disclosed within 90 days of the survey. The plan of correction is not, however, required since the laboratory's accreditation status is recognized in light of its condition-level compliance with the CLIA regulations.

o Explains to the laboratory that the Form HCFA-2567 will be forwarded to the accrediting organization for follow-up and that the accrediting organization may contact the laboratory concerning their correction.

o Prepares a Form HCFA-2567 and forwards the validation survey certification package to the RO.

2. The RO.--

o Notifies the laboratory in writing that the accrediting organization may contact it concerning the correction of deficiencies below the condition level (Exhibit 225);

o Copies all correspondence with the laboratory to the SA and accrediting organization.

o Copies the Form HCFA-2567 and any plan of correction to the CLIA component in CO.

6168. SURVEYS ACCEPTED FOR VALIDATION PURPOSES

A complaint survey of an accredited laboratory can be used as validation survey if it:

o Is conducted no later than 60 days after the accreditation organization's inspection; and

o Covers the entire laboratory, rather than the particular area(s) of the complaint.

In the unusual situation where there is information suggesting a substantial problem in an accredited laboratory, yet no prospect of a formal complaint, the contract survey can be used as an accreditation survey if it is performed no later than 60 days after the accreditation organization's inspection.

When a follow-up to a validation survey is performed, it should be considered as a follow-up, not as a validation survey.

In the case of a follow-up survey to a contract survey where one or more conditions were found out of compliance, and the SA performed a survey of the remaining areas of the laboratory no more than 60 days after the contract survey, the SA follow-up survey can be used as a validation survey.

6170. FORWARDING COMPLETED VALIDATION SURVEY INFORMATION TO CO

When the validation survey of an accredited laboratory and the follow-up activities have been completed, the RO will forward the following forms and other survey information to the CO CLIA component for use in the annual validation review:

- Form HCFA 2802A;
- Form HCFA 1557;
- Form HCFA 2567 including POC; and
- Copy of letter from SA to laboratory that states the findings of validation survey.

6172. NOTIFICATION REQUIREMENTS OF APPROVED ACCREDITATION ORGANIZATIONS

Responsibilities of each approved accreditation organization include notifying HCFA, on an ongoing basis, when certain situations occur. This information must be communicated in writing by the accreditation organizations within a specific time frame as required by the regulations and include the laboratory name, CLIA number, deficiencies identified, if applicable, and dates of identification or of any actions taken. The RO will record the date that accreditation organization notifies them of the information.

The following describes those situations that should be communicated to the RO:

- Immediate jeopardy situations (within 10 days);

- Newly accredited laboratories using the accreditation organization's program for CLIA compliance, including specialty and subspecialty information (within 30 days);

- Data related to unsuccessful PT performance and actions taken (within 30 days);

- Any adverse actions taken by the organization, i.e., denial, temporary loss, suspension, or withdrawal of accreditation, limitation of specialty/subspecialty, etc. (within 30 days); and

- Revisions in specialty/subspecialty testing (additions or deletions) in existing accredited laboratories using the accreditation organization for CLIA compliance (within 30 days).

Information relative to laboratories whose accreditation has been withdrawn or revoked will be helpful when assembling information for the annual laboratory registry. In addition, it may be used as a basis for a complaint or validation survey, as appropriate.

When accreditation has been removed from a facility, it then comes under HCFA's jurisdiction for CLIA purposes. The other mechanism by which a laboratory is no longer considered to be in compliance with the CLIA requirements by virtue of accreditation is after a complaint or validation survey. This results when the RO removes the certificate of accreditation due to Condition-level noncompliance that has not been corrected.

6174. BASIS FOR ACCREDITED LABORATORY COMPLAINT INVESTIGATION

The statutory basis for validation surveys of accredited laboratories on the basis of complaints or allegations of noncompliance is found in §353(e)(2)(D) of the PHSA. Regulations authorizing such surveys are found at 42 CFR, Part 493, Subpart E. 42 CFR Part 493.507(a)(2) provides that validation surveys are conducted in response to a substantial allegation of noncompliance. A substantial allegation of noncompliance refers to a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory, and raises doubts as to a laboratory's compliance with one or more CLIA Conditions.

Complaints made concerning accredited laboratories may be handled by the RO, SA or accrediting organization, depending on the nature of the complaint.

If the RO receives a substantial allegation of noncompliance concerning a CLIA accredited laboratory, the RO will review the complaint, and if it relates to the laboratory's compliance with one or more CLIA conditions, it will refer the complaint to the SA for investigation or carry out its own investigation. The RO will send a letter to the complainant, acknowledging the complaint and advising of the course of action, of the results of any investigation, if appropriate, and the corrective action taken.

If the SA receives a substantial allegation of noncompliance directly from a complainant about an accredited laboratory, it acknowledges receipt of the complaint, and advises the complainant of its intended course of action. The SA forwards a copy of the acknowledgment letter and the complaint to the RO.

If the SA or the RO determine that a complaint refers to a question or issue that is clearly beyond the purview of the CLIA survey and enforcement program, it advises the complainant of the limits of CLIA involvement and, if appropriate, mentions a possible alternative source of assistance. If the complaint indicates that a laboratory is operating without a CLIA certificate or certificate of accreditation, the SA send the complaint directly to the RO for review and action. The SA completes the HCFA-670, Survey Team Composition and Workload Report, for all complaint surveys and revisits.

In some cases, the nature of the complaint is such that the RO may wish to alert the accrediting organization itself to carry out its own investigation. In this case, the Accredited Laboratory Allegation(s) Report, Form HCFA-2878A (Exhibit 226), is completed by the RO and a copy sent to the accrediting organization for follow-up.

6176. RO DIRECTION OF ACCREDITED LABORATORY COMPLAINT INVESTIGATION

The RO prepares a Form HCFA-2802A, Request for Validation Survey of Laboratory (see Exhibit 107) and a HCFA-562, Medicare/Medicaid Complaint Form (Exhibit 75). The RO then forwards both forms to the SA with a copy of the allegation(s). The SA date stamps the forms with the date of receipt. The RO checks item 5 of the Form HCFA-2802A to indicate that it is a complaint survey of an accredited laboratory. Item 6 identifies the conditions, standards, specialty or subspecialty

directly related to the allegation to be investigated. The RO may, in addition, identify other related areas for review during the survey. When an investigation can be conducted through letter or telephone (e.g., personnel credentials), those means are to be used. (See 6136 for additional information)

The SA investigates a complaint within 2 days of receipt from the RO, if the RO determines that the complaint involves a potential immediate jeopardy to the individuals served by the laboratory or that of the general public. Otherwise, the RO will direct the SA to investigate non-immediate jeopardy complaints within 45 days.

The Form HCFA-562, which accompanies the allegation, specifies the appropriate time frame for action. If the SA receives the complaint directly, it determines the appropriate time frame.

6178. CONDUCTING COMPLAINT VALIDATION SURVEY OF AN ACCREDITED LABORATORY

The SA will conduct an unannounced validation survey of an accredited laboratory based on a substantial allegation of noncompliance. The SA assigns laboratory surveyors who normally conduct surveys of nonaccredited laboratories. Before beginning the complaint validation survey, the surveyor(s) requests the director (or charge person) to complete the Laboratory Authorization Form, if not already completed (Exhibit 108).

The SA does not disclose the identity of complainants and does not involve them in the investigation unless specifically directed by the RO. The SA conducts the complaint survey in accordance with the survey protocol in §6106 and uses the appropriate survey forms noted on the List of Documents in the Certification Packet (see Exhibit 63) and the Interpretive Guidelines as a guide when performing the inspection. The SA conducts a focused survey of only the Conditions related to the complaint. If the SA finds additional deficiencies during the course of the complaint investigation, it expands the scope of the survey to include additional standards or Conditions.

If a laboratory refuses to permit a complaint survey, follow the procedures in §6162.

At the exit conference, the SA informs the laboratory director of the deficiencies found. If the deficiencies do not pose an immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the SA prepares a Form HCFA-2567 and requests that the laboratory submit a PoC. The SA informs the laboratory that the Form HCFA-2567 will be made available to the public under the disclosure of survey information provisions. The SA indicates to the laboratory that the Statement of Deficiencies will be forwarded to the laboratory within 10 days and that the PoC must be returned to the SA within 10 days. Upon receipt of the survey information, the RO makes a determination of whether or not sanctions will be imposed against the laboratory. The SA does not monitor the correction of deficiencies unless requested to do so by the RO.

If the deficiencies pose an immediate jeopardy, the SA prepares the Form HCFA-2567 and notify the RO for immediate action. The SA forwards the Form HCFA-2567 to the RO within 2 days following the finding of an immediate jeopardy situation. Based on the information forwarded, the RO determines the most appropriate sanction to impose against the laboratory.

6180. FORWARDING INVESTIGATION REPORT TO RO

The SA will submit the appropriate information as specified in the List of Documents in the Certification Packet (see Exhibit 63), to the RO or through an update to the CLIA database within 30 days of completing the survey.

If the laboratory chooses not to submit a PoC when deficiencies are found, the SA reports any known information about the laboratory's efforts to correct deficiencies.

NOTE: In cases where immediate jeopardy exists, the SA submits all the appropriate information specified in the List of Documents in the Certification Package (see Exhibit 63), to the RO within 2 days.

6182. ACCREDITED LABORATORY FOUND IN COMPLIANCE FOLLOWING A COMPLAINT SURVEY

If after review of the documentation the RO determines that the accredited laboratory is in Condition-level compliance with all CLIA requirements, it officially notifies the laboratory and forwards a copy of this letter to the SA and the accreditation organization. This letter advises that the accreditation organization may contact the laboratory about correcting any deficiencies below Condition-level. This situation does not allow for any follow-up visits on deficiencies by the survey team.

6184. ACCREDITED LABORATORY FOUND NOT IN COMPLIANCE FOLLOWING A COMPLAINT VALIDATION SURVEY

If there are deficiencies that pose immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the laboratory may be subject to sanctions by the RO. Should the immediate jeopardy situation be corrected before the adverse action is taken or completed, the SA will advise laboratory that it will revisit the laboratory to inspect all remaining Conditions.

If the RO determines that the laboratory is out of compliance with one or more Conditions, but they do not pose an immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public, the RO notifies the laboratory that it is out of compliance and has been placed under SA monitoring jurisdiction (Exhibit 241). The letter also advises the laboratory that the SA will revisit to survey all the remaining conditions. A copy of the letter is provided to the accreditation organization.

The laboratory continues to be accredited by its accreditation organization and retains its CLIA certificate of accreditation during this monitoring period. The laboratory, however, becomes subject to the same requirements and survey and enforcement procedures applied to nonaccredited laboratories found out of compliance following a survey. The laboratory is monitored until it reaches Condition-level compliance or its certificate of accreditation is revoked.

Sample and Complaint Validation Surveys of CLIA-Exempt Laboratories

6200. VALIDATION SURVEYS OF CLIA-EXEMPT LABORATORIES - CITATIONS AND GENERAL DESCRIPTION

Section 353(p) of the PHSA permits the Secretary to exempt from CLIA all laboratories in any State that has demonstrated that its licensure laws or regulations related to laboratory requirements are equal to or more stringent than those requirements imposed by CLIA. The 42 CFR Part 493, Subpart E of the regulations, permits HCFA to approve or remove approval from specific State laboratory programs dependent upon specific criteria met. When HCFA approves a State laboratory program, a notice is published in the Federal Register, indicating the State for which an approval was granted, and the rationale for this decision. HCFA conducts sample and complaint validation surveys to ensure that requirements equivalent to CLIA requirements are continually being met by laboratories under the jurisdiction of approved State laboratory programs. HCFA periodically conducts validation reviews to evaluate the results of ongoing validation activities. As part of the validation review process, HCFA may conduct on-site evaluations of the State Laboratory program's offices to verify administrative policies and to assess the performance of personnel. As long as State laboratory program is approved, all laboratories in that State are exempt from meeting CLIA requirements. An approved State laboratory program must be exempt for no longer than 6 years, at which time it must reapply for continued exemption of its licensed laboratories. Validation surveys will be conducted by the RO.

A partial CLIA exemption may be granted to an approved laboratory licensure program in a State that does not license all of its facilities performing laboratory testing. If a State does not have a universal, all-inclusive licensure law, laboratories not licensed by the State remain under CLIA jurisdiction.

6202. VALIDATION SURVEYS OF CLIA-EXEMPT LABORATORIES - OBJECTIVES

CLIA-exempt laboratory validation surveys are intended to provide a reasonable evaluation of an approved State laboratory licensure program's performance and to assess the ongoing acceptability of exemption as an alternative to routine survey and certification activities. The RO has an important support responsibility, through the validation survey process, in gathering data about the actual implementation of an approved State laboratory licensure program and the laboratories licensed within the State. Additionally, the RO prepares a report on a comparative analysis of the findings of the SA and HCFA. (See §6216 Analysis of findings and Report.)

6204. SELECTION OF SAMPLE FOR VALIDATION SURVEYS OF CLIA-EXEMPT LABORATORIES

The sample of CLIA-exempt laboratories to be validated encompasses approximately 5% of State-licensed laboratories. (Refer to the annual budget call letter)

The RO obtains the laboratory licensure survey schedule from the SA. The RO selects the sample of laboratories to be validated using the criteria listed below and schedules the validation surveys to be conducted no later than 60 days after the State licensure inspection.

The RO selects laboratories based on the following criteria:

- Selecting from small, medium, and large laboratories;

- o Selecting laboratories that are geographically dispersed;
- o Avoiding the over-selection of laboratories with common ownership; and
- o Laboratories that encompass, in whole or in part (to the extent possible) the entire range of specialty and subspecialty testing.

HCFA CO may request that certain CLIA-exempt laboratories be included in the sample.

6206. PREPARING FOR SAMPLE VALIDATION SURVEY OF CLIA EXEMPT LABORATORIES

Validation surveys are typically announced. However, in cases where there is significant disparity in survey findings, the RO has the latitude to threat such a survey as a complaint validations survey. Validation surveys should be conducted, to the extent possible, on a rotating basis by RO laboratory surveyors so that no one surveyor conducts all the validation surveys.

The RO completes the survey in approximately the same time frame required for a laboratory of similar size and complexity undergoing a routine survey. All team members are required to survey a laboratory concurrently. To permit an independent compliance decision, The RO does not obtain a copy of the licensure survey findings prior to the RO compliance decision.

If a laboratory representative refuses to permit a validation survey, the RO contacts the State and requests that it contact the laboratory to explain the protocol and recommend that the State take enforcement action against the CLIA-exempt laboratory if appropriate.

6208. CONDUCTING VALIDATION SURVEYS OF CLIA EXEMPT LABORATORIES

In most validation activities, the RO relies upon the SA for the greater part of the survey tasks and functions. In the case of CLIA-exempt laboratories, this approach is not possible due to the potential for a conflict of interest. Therefore, the RO assumes direct responsibility for the entire validation survey process, unless CO utilizes a HCFA designated contractor, e.g., survey of cytology. While accreditation is voluntary, State licensure is mandatory for laboratories within the State that fall under the State's laboratory licensure program.

NOTE: A CLIA-exempt State may recognize a HCFA-approved accreditation program in lieu of State licensure. If so, a laboratory accredited by an approved accrediting organization may be subject to validation by the SA in the same manner as an accredited laboratory in a non CLIA-exempt State, i.e., it may be selected for validation by the SA from the schedule of accredited laboratories to be surveyed by the accrediting organization. The SA uses State licensure requirements to validate the accredited laboratory. At the RO's discretion, the RO may accompany the SA on these surveys.

The RO surveyor conducts the inspection in accordance with the survey protocol discussed in §6106. In addition validation surveys may be conducted concurrently with the State licensure survey as long as the Federal surveyors make independent observations and conclusions and complete all necessary documentation. The RO uses the appropriate survey forms and the interpretive guidelines (Appendix C) as a guide when performing the survey. The RO conducts an exit conference and informs the laboratory of the deficiencies found.

6210. RESULTS OF THE CLIA-EXEMPT VALIDATION SURVEY - RO AND SA RESPONSIBILITIES

A. Condition-Level Deficiencies with Immediate Jeopardy.--If the deficiencies identified are Condition-level and pose immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public:

1. The RO.--

o At the exit conference, informs the laboratory of its condition-level noncompliance status and explains to the laboratory that it does not meet the CLIA condition-level requirements and is subject to sanctions imposed by the SA;

o Prepares a Form HCFA-2567 and/or clearly documents the nature of the jeopardy and immediately (within 2 days) notifies the laboratory and the SA by overnight mail or facsimile (followed by mail) of the findings (See Exhibits 227 - 228). A copy of this communication is sent to the CLIA component in CO.

o For concurrent surveys, assures that the State has appropriately notified the laboratory of any deficiencies that pose immediate jeopardy before leaving the facility.

2. The SA.--

o Takes the appropriate enforcement actions based on the enforcement policies of the State licensure program.

3. The RO.--

o Follows up with the SA within approximately 15 days to verify the appropriate action has been taken or that the jeopardy situation has been corrected. If appropriate enforcement action has not been taken by the SA within 23 days and the jeopardy situation remains, the RO may seek a temporary injunction or restraining order and be granted without bond, pending issuance of a final order. Refers the case to the RO of the General Counsel and requests that a suit be filed in the United States District Court for the district in which the laboratory is located to enjoin continuation of the specific activity that is causing hazard or to enjoin the continued operation of the laboratory (See Exhibits 229 - 230.)

B. Condition-Level Deficiencies with No Immediate Jeopardy.--

1. The RO.--

o At the exit conference, informs the laboratory of its condition-level noncompliance and explains to the laboratory that it does not meet the CLIA condition-level requirements and is subject to sanctions and follow-up by the SA.

o Within 10 days of completing the survey, prepares a Form HCFA-2567 and letter notifying the laboratory and the SA of the findings and of SA follow-up (See Exhibits 231 - 232).

2. The SA.--

o Takes the appropriate enforcement actions based on the policies of the State licensure program. The SA requests an acceptable plan of correction from the laboratory and when received, forwards a copy of it to the RO.

3. The RO.--

o Notifies the laboratory and the SA of the laboratory's compliance status. If appropriate enforcement action has not been taken by the SA and/or the condition-level noncompliance remains, the RO may seek a temporary injunction or restraining order against the continuation of that activity by the laboratory.

C. Deficiencies Found below the Condition-Level

1. The RO.--

o At the exit conference, informs the laboratory that it is in condition-level compliance with the CLIA requirements, but that standard level deficiencies are identified.

o Prepares a Form HCFA-2567 and notifies the laboratory (See Exhibit 243) and the SA (See Exhibit 244) within 10 days of the findings and of SA follow-up. The laboratory is encouraged to submit a plan of correction since the HCFA-2567 will be made available to the public in accordance with the Federal Freedom of Information Act (FOIA) disclosure provisions and can be publicly disclosed within 90 days of the survey. The plan of correction is not, however, required since the laboratory's State licensure status is recognized in light of its condition-level compliance with the CLIA regulations.

2. The SA.--

o Monitors the correction of the cited deficiencies based on the policies of its licensure program.

D. Concurrent Validation Surveys.--When validation surveys are done concurrently with State licensure surveys:

The RO.--

o Assures that the SA has appropriately notified the laboratory of any deficiencies that pose immediate jeopardy before leaving the facility.

o Prepares a Form HCFA-2567 for all identified deficiencies. If the SA cites all deficiencies identified by the RO, it is not necessary for the RO to forward its copy of the Form HCFA-2567 to the laboratory or the SA;

o For deficiencies not cited by the SA, prepares a Form HCFA-2567 for those deficiencies and forwards a letter and the HCFA-2567 to the laboratory and to the State advising the laboratory that the SA will follow-up the deficiencies.

o When necessary, requests the State to obtain an acceptable POC and forward a copy to the RO, and directs the State to take the appropriate enforcement action for any Condition-level deficiencies, if necessary, and to report the enforcement action taken to the RO (See Exhibit 232)

o Documents the file and notifies the CLIA component at CO, if the State refuses to take appropriate enforcement action. Refusal constitutes a breach in agreement between HCFA and the State and may jeopardize the approval and/or renewal of a State's laboratory licensure program.

6212. ONSITE OBSERVATION OF STATE LABORATORY PROGRAM OPERATIONS

42 CFR 493.517(f) allows HCFA to conduct onsite inspections of the State's laboratory program offices and operations. The RO should include one or more onsite evaluations of the State's

operations each year as part of the exemption evaluation process. The purpose of the onsite inspections is to verify the representations made by the State in their application for CLIA exemption. Additionally, the RO should assess the State's compliance with its own policies and procedures as approved by HCFA.

An onsite inspection may include, but is not limited to, an evaluation of the following:

- Survey workload,
- Enforcement activities,
- Complaint management,
- Validation surveys of accredited facilities,
- Surveyor competency,
- Surveyor training and continuing education,
- Proficiency testing monitoring,
- Internal quality improvement activities, and
- Financial management.

Data may be gathered through employee interviews, documentation review, meeting attendance, or other means. Refusal by the State to allow an onsite inspection or poor performance in the management of the above activities may jeopardize the renewal of a State's CLIA exemption.

6214. PROCESSING VALIDATION SURVEY RECORDS

The RO inputs the survey information into the OSCAR system within 45 days of completing the survey. The applicable documents should be completed and processed (See Appendix C).

6216. ANALYSIS OF FINDINGS AND REPORT

In a CLIA-exempt State, the RO not only performs the validation surveys as described above, but also prepares a summary report on the comparative analysis of the State licensure findings vs. RO findings, based on condition-level compliance. The RO submits this report to the CLIA component in CO, which incorporates the RO's report into its annual report for Congress.

6218. NOTIFICATION REQUIREMENTS OF CLIA-EXEMPT STATES

Responsibilities of each CLIA-exempt State include notifying HCFA, on an ongoing basis, when certain situations occur. This information must be communicated in writing by the CLIA-exempt States within a specific time frame as required by the regulations and includes the laboratory name, CLIA number, deficiencies identified, if applicable, and dates of identification or of any actions taken. The RO should record the date of the CLIA-exempt State's notification of the information.

The following describes those situations that the CLIA exempt State should be communicated to the RO:

1. Immediate jeopardy situations (within 10 days);

2. Newly licensed laboratories, including specialty and subspecialty information (within 30 days);

3. Data related to unsuccessful PT performance and actions taken (within 30 days);

4. Any sanctions taken by the State i.e., denial, withdrawal, or revocation of State licensure, limitation of specialty/subspecialty, etc. (within 30 days); and

5. Revision in specialty/subspecialty testing (additions, deletions) in existing CLIA-exempt laboratories (within 30 days).

Information relative to laboratories whose licensure has been withdrawn or revoked will be helpful when the RO assembles information for the annual laboratory registry and for use in the evaluation report of the State's operations.

6220. CLIA-EXEMPT LABORATORY COMPLAINT INVESTIGATIONS - GENERAL

A substantial allegation of noncompliance refers to a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles). The complaint, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory and raises doubts as to a laboratory's compliance with one or more CLIA requirements.

6222. REVIEW OF CLIA-EXEMPT LABORATORY COMPLAINTS

The RO reviews all complaints received to determine what type of investigation or referral is appropriate. If the RO receives a substantial allegation of noncompliance directly from a complainant about a CLIA-exempt laboratory, it acknowledges the receipt of the complaint and advises the complainant in writing of its intended course of action.

Complaints received by the RO that raise doubt as to a laboratory's compliance with one or more CLIA requirements are investigated by the RO. The RO must refer these to the SA. (See 42 CFR Part 493.517(a).) Complaints received by the CLIA-exempt SA which raise doubts as to a laboratory's compliance with CLIA or State licensure requirements are investigated by the SA. The SA must notify the RO when a licensed laboratory has in any way been sanctioned or has had its license withdrawn or when immediate jeopardy is identified. The SA should forward a copy of each complaint to the RO and indicate how it was resolved.

If the RO determines that a complaint raises a question or issue that is clearly beyond the purview of the CLIA survey and enforcement program or the State laboratory licensure program, the RO advises the complainant of the limits of its involvement and, if appropriate, mentions a possible alternative source of assistance.

The RO establishes a file for complaints and logs the actions. The system may be manual or automated, but must facilitate tracking and control of complaints. The number and type of complaints, along with the actions taken and status, are to be included in the RO's annual report to the CLIA component at CO.

6224. CONDUCTING COMPLAINT VALIDATION SURVEY FOR CLIA-EXEMPT LABORATORIES

The RO will complete Form HCFA-562, Medicare/Medicaid Complaint Form, for every complaint investigation in a CLIA-exempt laboratory and will identify the areas related to the allegation that should be surveyed. When an investigation can be conducted via telephone (e.g., personnel credentials), the RO should do so. The RO obtains the following information for every allegation:

- Complainant's name and address (unless complainant requests anonymity). Do not disclose the identity of the complainant to the laboratory;
- Laboratory's name and address; and
- Description of problem, involving names, places, and dates.

The RO will use whatever form or format is already being used for recording or summarizing an allegation. The Form HCFA-562 is not intended for this purpose. The RO will investigate all complaints within 2 days of receipt, if it determines that the complaint involves a potential immediate jeopardy to the individuals served by the laboratory or that of the general public. Otherwise, the RO investigates no- immediate-jeopardy complaints within 45 days by survey, phone, etc.

The RO will conduct an unannounced complaint survey of a CLIA-exempt laboratory based on a substantial allegation of noncompliance. If a laboratory representative refuses to permit a complaint survey, the RO contacts the State and requests that it contact the laboratory to explain the protocol and if necessary suggest that the State take enforcement action against the CLIA-exempt laboratory. The RO conducts the complaint survey in accordance with the survey protocol and uses the appropriate survey forms specified in Exhibit 63 and the interpretive guidelines, Appendix C.

Initially, the RO focuses the survey only on the condition(s) or requirement(s) related to the complaint area(s). If the complaint is substantiated or if additional deficiencies are found during the course of the investigation, the RO expands the scope of the survey to include additional standards, conditions, and other CLIA requirements. (See 42 CFR Part 493.517(a)(2).) If the compliant is not substantiated the RO notifies the laboratory that it is in compliance with the CLIA condition (Exhibit 243). Also the RO notifies the State laboratory program of the condition-level compliance (Exhibit 244).

At the exit conference, the RO informs the laboratory of the deficiencies found. If the deficiencies pose immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the RO notifies the State and the laboratory within two days by overnight mail and include a copy of the Form HCFA-2567. The RO directs the State to take the appropriate enforcement action. (See Exhibits 231 and 228). The RO should follow-up with the State within 15 days of its notification to the laboratory to verify that the recommended enforcement action has either been taken against the laboratory or that the laboratory has achieved compliance with CLIA requirements.

If the State fails within 23 days of the RO's notification to them to take the appropriate enforcement action in cases where it has been determined that the operations of the laboratory pose an immediate jeopardy to public health, a temporary injunction or restraining order may be sought and granted without bond, pending issuance of a final order. The RO refers the case to the General Counsel within its region and request that a suit be filed in United States District Court for the district in which the laboratory is located to enjoin continuation of the specific activity that is causing the hazard or to enjoin the continued operation of the laboratory. (See Exhibits 229 and 230.)

If the deficiencies do not pose immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the RO prepares a Form HCFA-2567 and forwards a letter along with the Form HCFA-2567 to the laboratory within ten days of completing the survey. The RO advises the laboratory that the State is responsible for taking any enforcement action, if necessary, and monitoring the correction of the deficiencies and that the State will provide a report to the RO. (See Exhibit 231.) The RO informs the laboratory that the results of the survey will be made available to the public in accordance with the Federal Freedom of Information Act (FOIA) disclosure provisions.

Also, within 10 days after completing the survey, the RO notifies the State in writing of the laboratory's deficiencies. If necessary, the RO requests that it obtain an acceptable PoC and forwards a copy to the RO. The RO directs the State to take the appropriate enforcement action, if necessary, and to report the action taken to the RO. (See Exhibit 228.)

The RO completes a Form HCFA-670, Survey Team Composition and Workload Report, for all complaint surveys. Any subsequent revisits resulting from a complaint investigation that are conducted should not be documented on the Form HCFA-670.

If a State fails to take appropriate enforcement action in no immediate jeopardy situations, the RO documents its files accordingly and notifies CO. Failure to take the necessary enforcement action will be documented in the annual validation review and may subsequently jeopardize current or future approval of the State's laboratory licensure program.

Other Activities

6230. STATE AGENCY QUALITY IMPROVEMENT PROGRAM (SAQIP)

The SA in partnership with the RO participates in the SAQIP, which includes improvement in the SA's performance of CLIA-related activities (See Chapter 8 for discussion of SAQIP).

6232. FEDERAL MONITORING SURVEY (FMS) SELECTION

The primary purpose of the FMS system is to monitor SA performance through comparison of findings from direct Federal survey with State survey findings. Monitoring of problem providers is a secondary goal of the system. The RO's FMS strategy should be consistent with this approach. Actual monitoring survey targets and allocation requirements will be established at the beginning of each fiscal year through a CO component negotiation process. As a basic rule, however, the RO does not include in the FMS sample selection any facility against which adverse action has been initiated by the State survey agency.

6234. FMS OF LABORATORIES - DEFINITIONS AND PURPOSE

A. Definition.--An FMS is any survey performed by a RO laboratory specialist of any laboratory meeting the CLIA definition of a laboratory for purpose of monitoring State performance. A laboratory is any facility that test human specimens for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings (refer §§6000 and 6150). Laboratories under direct Federal jurisdiction are exempt from the FMS survey process (refer §6022). Laboratories hold a certificate of waiver or a PPM procedures, which are not subject to routine certification surveys, are also exempt from FMS surveys.

B. Purpose.--The RO conducts the survey to:

- Monitor SA performance in interpreting and applying CLIA requirement and the survey process for laboratories;
- Identify training/or technical assistance needs of surveyors;
- Identify problems that surveyors and/or laboratories encounter in implementing Federal regulations and survey procedures; and
- Uncover and correct problem that exist in individual States, laboratories, or on individual surveys.

C. Scope of FMS Surveys.--

1. Full Survey.--This is a survey of all applicable CLIA conditions and/or standards for laboratories.

2. Partial Surveys.--This is a survey of selected CLIA conditions and/or standards for laboratories.

D. Types of FMS Surveys.--

1. Observational surveys is proposed as an alternative method of evaluating the use of quality assurance with determining the laboratory's compliance with requirements of the appropriate CLIA subparts and to determine areas of clarification or change needed for existing policies and procedures

and identifying training needs for surveyors. Observational surveys give the RO a broader method to assess SA performance and training needs. The RO and SA surveyors communicate about findings, observations, decisions and regulatory interpretations during the survey in a collaborative and cooperative environment.

2. Participatory surveys is proposed as a method of evaluating the use of quality assurance with determining the laboratory's compliance with requirements of the appropriate CLIA subparts and also to determine areas of clarification or change needed for existing policies and/or procedures and identifying training needs for SA surveyors. The participatory survey offers a collaborative for the RO & SA. The RO surveyor and SA surveyors communicate and compare finding, observations, decisions and regulatory interpretations during the survey in a collaborative and cooperative environment.

6236. FMS PROCEDURES

Following is a RO guide for the scheduling and performance of monitoring surveys.

A. Scheduling of Surveys.--The RO conducts FMS surveys on an announced or unannounced basis. In the case of an announced survey, the RO notifies the facility of the upcoming survey using the model letter in Exhibit 62.

B. Survey Findings.--The RO ends each Federal survey with a standard exist conference with appropriate facility staff and discusses findings in general terms as well as specify any deficiencies that could significantly affect the health and safety of individuals or result in adverse action.

If the RO determines that CLIA Conditions are out of compliance, see §§6250-6299 for enforcement process. The RO is responsible for subsequent enforcement actions under these circumstances. However, the RO may request that the SA do any necessary follow-up visits except for Federal jurisdictional surveys. The RO forwards to the SA the survey findings and copies of all correspondence with the entity.

If the Federal team does not cite any CLIA conditions but identifies deficient standards, the RO prepares and forwards the Form HCFA-2567 and a comparative analysis to the SA and place a copy of the Form HCFA-2567 in the laboratory certification file. The RO requests that the SA obtain a POC from the facility, and monitors the SA's follow-up activities. The RO may wish to work with the institution directly if the seriousness of the findings warrant it.

6238. REPORTS OF FINDINGS OF FMS

To provide accurate information on both the number and types of monitoring surveys the RO completes the Form HCFA-534 for entry in OSCAR as well as a Form HCFA-670. Data from the HCFA-670 is entered into the system for each survey performed, regardless of the type or extent of the survey, or the size of the survey team. For CLIA surveys, the Form HCFA-670 will capture SA time, RO time, CO (administrative) time, and appeals time expenditures. This more comprehensive accounting of time is necessary to meet the self-funding requirement of CLIA.

6240. OTHER SPECIAL PURPOSE FEDERAL SURVEYS - DEFINITIONS

1. Validation survey of accredited laboratory or CLIA-exempt laboratory is a survey of an accredited laboratory or a CLIA-exempt laboratory based on a representative sample or in response to a substantial allegation of non compliance to determine compliance.

2. Federal jurisdictional survey is a Federal survey to assess laboratory performance and to determine whether a laboratory meets all CLIA requirements for the tests which the lab conducts. It is used as the basis for approving a laboratory where HCFA has indicated that the SA should not

have jurisdiction over the laboratory. Surveys conducted by Federal personnel include Federally operated laboratories, and State operated laboratories. When conducting these surveys, the RO performs all functions performed by the SA for CLIA laboratories, including ensuring that the laboratory is enrolled in an approved PT program and monitoring their performance in the PT program. Survey of a laboratory outside the U.S. will be determined by CO if it performs laboratory tests on human specimens referred to it by a laboratory in the U.S. Or its territories.

3. Complaint Survey is a survey conducted to investigate an allegation of laboratory noncompliance with one or more CLIA requirements.

4. Follow-up survey is conducted to determine the status of corrective action, based on deficiencies cited on the Form HCFA-2567. A contact, i.e., telephone or mail in lieu of an on-site follow-up survey, may be conducted to ascertain the status of a facility which has received notice from the RO and has alleged correction of the deficiency or deficiencies.

Adverse Actions

6250. PURPOSE OF AND BASIS FOR ENFORCEMENT ACTION

Laboratories holding any type of CLIA certificate are subject to enforcement actions under the authority of §353 of the Public Health Service Act (PHSA) and §1846 of the Social Security Act. 42 CFR Part 493, Subpart R, sets forth the enforcement procedures for laboratories.

A. Purpose.--The enforcement process serves the following purposes:

- To protect all individuals served by a laboratory against substandard testing of specimens;

- To safeguard the general public against health and safety hazards that might result from laboratory activities; and

- To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.

B. Basis for Enforcement.--CLIA enforcement actions are based on:

- Deficiencies found during an onsite laboratory survey or through review of materials submitted by the laboratory, e.g., personnel qualifications;

- Unsuccessful participation in PT;

- Improper referral of PT;

- Failure to comply with notification requirements; or

- Improper actions of laboratory's owners, operators or employees, which include:

  + Misrepresentation in obtaining a CLIA certificate;

  + Performance of, or representing the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;

  + Failure to comply with the certificate requirements and performance standards;

  + Failure to comply with reasonable requests by HCFA or its designee for any information or work on materials that is necessary to determine the laboratory's continued eligibility for CLIA certification or continued compliance with performance standards set by HCFA;

  + Refusal of a reasonable request by HCFA or its agent for permission to inspect the laboratory including its operation and pertinent records during the hours that the laboratory is in operation;

+ Violation or aiding and abetting in the violation of any provisions of CLIA and its implementing regulations; and

+ Owning or operating, within the preceding two-year period, a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

6252. DEFINITIONS/TERMINOLOGY - ENFORCEMENT

A. Day.--Unless otherwise stated, day always means calendar day.

B.PT Scores.--The HCFA approved PT program will determine the overall and individual analyte scores following the grading criteria defined in 42 CFR Part 493, Subpart I.

C. PT Survey.-- A module or grouping of samples marketed as a unit by PT programs. Programs typically offer several survey kits which include different samples for the same specialty, subspecialty, analyte, or test.

D. Repeat Deficiencies.-- The same Condition-level deficiencies found in three consecutive surveys, for the purposes of suspension of all Medicare payments.

E. Significant Hazard to the Public Health.--This is a deficiency that may cause harm to members of the community who are not necessarily patients served directly by the laboratory, e.g., incorrect reporting of accurate test results with respect to communicable diseases. The term is equivalent to immediate jeopardy for patients served by the laboratory.

F. Testing Event.--This is a PT program's scheduled submission to a laboratory of survey samples for a regulated specialty, subspecialty, analyte, or test. A minimum of two testing events per year are required for the mycobacteriology subspecialty. All other specialties, subspecialties, analytes, and tests require three testing events per annum except cytology.

G. Training and Technical Assistance.--This is a sanction option separate from principal and alternative sanctions that may be applied alone or in addition to other sanctions when a laboratory is not in compliance with the CLIA PT requirements. HCFA may require the laboratory to undertake formal training of its personnel or to obtain necessary technical assistance, or both, in order to successfully resolve the noncompliance. An educational focus is recommended for initial unsuccessful PT performance if it has not resulted in an immediate jeopardy situation.

6254. DENIAL OF FORM HCFA-116 FROM PROSPECTIVE LABORATORY OR DENIAL OF LABORATORY'S CLINICAL LABORATORY APPLICATION FORM HCFA-116 TO TEST IN NEW SPECIALTIES OR SUBSPECIALTIES

If Clinical Laboratory Application Form HCFA-116 for any CLIA certificate is denied, the RO prepares a notice to the laboratory outlining:

o The decision and the reason for the denial, citing provisions of the law or implementing regulations not met;

o The laboratory's appeal rights;

o The fact that the laboratory cannot operate or receive payment under Medicare or Medicaid unless the denial is overturned at the conclusion of the administrative appeals process and a CLIA certificate is issued; and

- o The procedures to follow for a reconsideration.

The denial notice must be signed by the RO delegated to adjudicate denials.

6256. VOLUNTARY WITHDRAWAL FROM CLIA PROGRAM

A. Laboratory Gives Notification of Going Out of Business.--A laboratory may voluntarily withdraw from all testing, and, therefore, relinquish its CLIA certificate and go out of business by notifying the RO or SA of its intent, in writing. If the SA learns that a laboratory intends to close, the SA notifies the RO by letter, including the projected date of closure. Any correspondence received from the laboratory and any other pertinent document(s) are submitted to the RO. After receiving notice, the RO will communicate with the laboratory regarding the closure, and will notify carriers, fiscal intermediaries (FIs), and the State Medicaid agency.

B. Laboratory Gives No Notification of Going Out of Business.--If a laboratory voluntarily withdraws from all testing, and refuses new requests for testing, it voluntarily relinquishes its CLIA certificate. If the SA learns that a laboratory may be going out of business, it verifies the situation and notifies the RO of its findings. The RO will communicate with the laboratory regarding the closure and will provide copies of any such correspondence to the SA, the State Medicaid Agency, and to the FIs or carriers, as appropriate. The SA notifies the RO immediately if it learns that a laboratory has already closed.

C. Voluntary Withdrawal When Revocation Is Pending.--The RO may proceed with the revocation despite the laboratory's withdrawal, if the RO decides that the laboratory's owner or operator should be subject to the 2-year prohibition against owning or operating a laboratory that is triggered by revocation.

If the RO decides to proceed with the revocation, it prepares a notice to the laboratory explaining that, although it has withdrawn from the CLIA program, its CLIA certificate will remain active until the revocation takes effect so that HCFA may exercise its right to take its enforcement action to conclusion. The RO will restate in the notice the laboratory's appeal rights mentioned in the notice of sanction.

If the RO decides to discontinue the revocation, it processes the withdrawal as when revocation is not pending.

D. Voluntary Withdrawal When Revocation Is Not Pending.--The RO prepares a notice to the laboratory in accordance with 42 CFR Part 489.52, with copies to the carrier and State Medicaid agency. It annotates the Form HCFA-1539 to indicate voluntary termination, if applicable.

6258. VOLUNTARY WITHDRAWAL OF CERTIFICATION TO TEST IN SPECIALTY OR SUBSPECIALTY

A laboratory that discontinues testing in a specialty or subspecialty may voluntarily withdraw its certification to test in that specialty or subspecialty by notifying the RO or the SA in writing.

A. Voluntary Withdrawal When Limitation Is Pending.--The RO may proceed with the limitation if it decides that the laboratory's performance warrants inclusion on the annual laboratory registry and media notification which are triggered by imposition of an adverse action.

If the RO proceeds with the limitation, it notifies the laboratory that its certification to test in a specialty or subspecialty will remain active until the limitation takes effect so that HCFA can exercise its right to take its enforcement action to conclusion. The RO informs the laboratory that, after that

time, it will be assessed a fee for a revised certificate which it will subsequently be issued. The laboratory's appeal rights are reiterated in the notice of sanction if the RO decides to discontinue the limitation, it proceeds as if limitation was not pending.

B. Voluntary Withdrawal When Limitation Is Not Pending.--The RO assesses the laboratory the appropriate fee for the revised certificate, issues the laboratory its revised certificate, and notifies the carrier and State Medicaid agency of the change.

6260. REQUESTS TO CHANGE CERTIFICATE TYPE

A. Requests to Change Certificate Type When Enforcement Action Is Pending.--The RO proceeds with the enforcement action proposed against a laboratory's existing certificate if the laboratory's deficiencies warrant it.

If the RO proceeds with the enforcement action, the RO notifies the laboratory that its certificate will remain active until the enforcement action becomes effective, at which time the request will be acted upon.

If the enforcement action is discontinued, the RO proceeds as if the enforcement action was not pending.

B. Requests to Change Certificate Type When Enforcement Action Is Not Pending.--The RO assesses the laboratory the appropriate certificate fee, issues the laboratory a new certificate, notifies the carrier and State Medicaid agency of the change, and schedules the laboratory for survey, if applicable.

6262. CLIA CONDITIONS NOT MET - ENFORCEMENT OPTIONS FOR ALL LABORATORIES

HCFA may impose one or more of the sanctions specified in this section on any laboratory that is out of compliance with one or more CLIA requirements.

A. Principal Sanctions.--HCFA may impose any of the three principal CLIA sanctions, which are:

- o Limitation of the CLIA certificate;
- o Suspension of the CLIA certificate; or
- o Revocation of the CLIA certificate.

B. Alternative Sanctions.--HCFA may impose one or more of the following alternative sanctions on any laboratory in lieu of or in addition to imposing a principal sanction:

- o Directed PoC and directed portion of a PoC;
- o State onsite monitoring; and/or
- o Civil money penalty.

EXCEPTION: Alternative sanctions may not be imposed on a laboratory that has a certificate of waiver because there are no Condition-level requirements for the waived tests. These laboratories are not inspected for compliance with Condition-level requirements.

For laboratories approved to receive Medicare payment, sanctions also include:

- Suspension of part of Medicare payment;
- Suspension of all of Medicare payment; or
- Cancellation of Medicare payment

C. Civil Suit.--HCFA may bring suit in the appropriate U.S. District Court to enjoin continuation of any specific activity that is causing a significant hazard, or to enjoin the continued operation of the laboratory itself (including a CLIA-exempt laboratory that has been found to have deficiencies during a validation survey), if HCFA believes that continuation of the specific activity or laboratory operations would constitute a significant hazard to the public health. Upon proper showing, the court issues a temporary injunction or restraining order without bond against continuation of the activity or operations.

D. Criminal Sanctions.--An individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined. An intentional violation is knowing and willful noncompliance with any CLIA requirement. The RO refers suspected instances of intentional violations to OIG.

E. Unsuccessful Participation in PT: Training and Technical Assistance Option.--If a laboratory's participation in PT is unsuccessful, the RO may require the laboratory to undertake special training of its personnel, or to obtain necessary technical assistance, or both. This enforcement action is separate from all other principal and alternative sanctions available for all laboratories. The authority to impose this remedy in lieu of or in addition to other sanctions is discretionary with the RO, and it continues after the CLIA phase-in period has expired. An educational focus is recommended for initial unsuccessful PT performance that does not cause immediate jeopardy.

F. Reissuance of Certificates to Laboratories Found Out of Compliance.--A laboratory that has been found out of compliance with one or more CLIA Condition(s) may be reissued a CLIA certificate before the expiration date when:

- Alternative sanctions or training and technical assistance or both are imposed; or
- There is no immediate jeopardy to individuals served by the laboratory or to the general public health and a principal sanction or civil money penalty has been imposed and the laboratory's appeal of that sanction, including revocation, is pending when its current certificate expires.

A certificate or certificate of accreditation may also be reissued to a laboratory that has been found out of compliance if the laboratory holds a certificate or certificate of accreditation that has been subject to a principal sanction or civil money penalty and the laboratory's appeal of that sanction is pending when its current certificate expires.

Any certificate issued under any or these circumstances is subject to all principal and alternative sanctions.

6264. CLIA CONDITIONS NOT MET - PRINCIPAL AND ALTERNATIVE SANCTIONS FOR LABORATORIES THAT PARTICIPATE IN MEDICARE

CLIA certification is mandatory for all laboratories, regardless of payment, while enrollment in Medicare and Medicaid is voluntary.

The Medicare program has for many years required that noncompliant suppliers, including laboratories, be subject to enforcement actions under the Medicare statute before, in most cases, there is an opportunity for a hearing. CLIA permits imposition of alternative sanctions other than a civil money penalty prior to a hearing and also permits the suspension or limitation of the CLIA certificate prior to a hearing if:

- o Immediate jeopardy exists;
- o The laboratory has refused a reasonable request for information, materials, or work (e.g., failure to conduct PT) on materials necessary to determine compliance with CLIA; or
- o The laboratory has refused HCFA or its agent(s) permission to conduct a survey.

Although the Federal health and safety requirements are now the same for Medicare and CLIA, failure to meet CLIA requirements may result in additional enforcement actions under Medicare, since both the Public Health Service Act and the Social Security Act apply to these facilities. These Medicare sanctions are described below.

A. Principal Sanction.--HCFA may cancel the laboratory's approval to receive Medicare payment for its services.

1. Basis for Cancellation.--HCFA always cancels a laboratory's approval to receive Medicare payment for its services if HCFA suspends or revokes the laboratory's CLIA certificate.

Cancellation of Medicare approval to receive Medicare payment for its services applied to those specialties and subspecialties that are affected by a limite CLIA certificate.

HCFA may cancel the laboratory's approval to receive Medicare and Medicaid payment for its services under any of the following circumstances:

- o The laboratory is out of compliance with a Condition including failure to meet PT requirements;
- o The laboratory fails to submit an acceptable PoC within an appropriate timeframe; or
- o The laboratory fails to correct lower level deficiencies within the timeframes specified in the PoC, which cannot extend beyond 12 months from the last date of survey that identified the deficiencies.

2. Effective Date.--Medicare cancellation takes effect after proper written notice to the laboratory (five days before the effective date of the sanction for immediate jeopardy and 15 days before the effective date if there is no immediate jeopardy), which includes the opportunity to respond. The cancellation is not delayed because the laboratory has appealed and the hearing or hearing decision is pending.

3. Effect of Cancellation on Other Medicare Payment Sanctions.--Cancellation of Medicare approval terminates any other Medicare payment sanction, i.e., suspension of all or part of Medicare payments, regardless of the timeframes originally specified for the other sanction.

4. Effect of Cancellation of Medicare on Laboratory's Eligibility to Receive Medicaid Payments.--As provided in §1902(a)(9)(c) of the Act, payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that meet CLIA requirements or is licensed by a State whose licensure program has been approved for CLIA exemption by HCFA.

B. Alternative Sanctions.--

1. Suspension of Part of Medicare Payments.--HCFA may impose this sanction in the following situations:

o The laboratory has Condition-level deficiencies with respect to tests in one or more specific specialties or subspecialties; and

o The laboratory agrees not to charge Medicare beneficiaries, their private insurance carriers, the fiscal intermediary (FI), or carrier for those services for which payment is suspended. The laboratory may choose to make this agreement in return for not having its Medicare approval cancelled immediately.

After proper written notification, the RO will inform the appropriate Medicare carrier or intermediary to suspend Medicare payment for services furnished on and after the effective date of the sanction for those specialties or subspecialties for which the laboratory is out of compliance. The sanction remains in effect until the laboratory corrects the condition-level deficiencies or HCFA cancels the laboratory's approval to receive Medicare payment, but never beyond 12 months from the last date of the survey which identified the deficiencies; one or the other must occur. If the laboratory corrects all condition-level deficiencies, the RO resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected. If all deficiencies are not corrected within the timeframes specified in the PoC, which cannot exceed 12 months, the RO cancels the laboratory's approval to receive Medicare payment for its services.

2. Suspension of All Medicare Payments.--HCFA suspends Medicare payment for all tests in all specialties and subspecialties that are performed on or after the effective date of the sanction in any of the following situations:

o The laboratory has not corrected its Condition-level deficiencies included in the PoC within three months from the last date of survey; or

o The laboratory has had the same Condition-level deficiency(ies) during three consecutive biennial cycles.

The laboratory agrees not to charge Medicare beneficiaries, their private insurance carrier, the FI, or carrier for those services for which payment is suspended. The laboratory also agrees to waive any rights to appeal Medicare claims, that are denied during the period of suspension. The laboratory may make this agreement in return for not having its Medicare approval cancelled immediately.

HFCA suspends Medicare payment for all tests performed on or after the effective date of the sanction. This sanction remains in effect until the laboratory corrects all Condition-level deficiencies, but never beyond 12 months from the last date of the survey which identified the deficiencies.

If the laboratory corrects all Condition-level deficiencies, the RO resumes Medicare payment and eligibility to receive Medicaid payment, effective for all services furnished on or after the date the deficiencies are corrected. If all deficiencies are not corrected by the end of the 12-month period specified above, the RO cancels the laboratory's approval to receive Medicare payment for its services.

3. Exception for Laboratories with Certificates of Waiver.--Alternative sanctions are not imposed on laboratories with certificates of waiver that receive Medicare payments for their services, because there are no Condition-level requirements for the these tests. However, the fact that a deficiency is not at the Condition-level does not preclude taking adverse action based on the

provisions contained in 42 CFR Part 493.1840. For example, if a laboratory is not following a manufacturer's instructions it is not considered to be meeting the requirements in subpart B and the certificate can be suspended, revoked, or limited. If a laboratory is found to be performing non-waived tests under its certificate of waiver, its certificate may be suspended or revoked. When a laboratory's certificate of waiver is revoked or suspended, its approval to receive Medicare payment for its services is concurrently cancelled.

4. Effect on Medicaid Participation.--Payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that meets CLIA conditions or is operating under a CLIA certificate.

6266. FAILURE TO FURNISH NOTIFICATION OF CHANGES

If a laboratory fails to meet the notification of change requirements, RO may impose a sanction.

A. Notification Required Within 30 Days.--A laboratory must notify HCFA or the State survey agency within 30 days of any changes in its:

- o Ownership;
- o Name;
- o Location;
- o Director; or
- o Technical Supervisor

B. Notification Required Within 6 Months.--A laboratory with a CLIA certificate must notify the SA (or the RO for Federal jurisdictional surveys) within six months of any changes in specialty or subspecialty testing that is not included in the laboratory's certification. However, no Medicare payment may be made to the laboratory until proper notification has occurred.

For a laboratory with a certificate of accreditation, the notification of these changes must be made to its accreditation organization.

NOTE: A laboratory with a registration certificate is not required to report such changes, since registration certificates do not specify the specialties/subspecialties of services offered.

C. Notification Requirements for Laboratories with Certificate of Waiver.--

1. Expansion to Include Tests Other Than Waived Tests or Examinations.--A laboratory with a certificate of waiver may not perform any examination or procedure not listed in the waived test category until it has reapplied and has been issued the appropriate certificate (i.e., certificate for PPM procedures or registration certificate) that covers the additional examinations or procedures requested by the laboratory.

2. Changes in Waived Tests or Examinations.--For a laboratory with a certificate of waiver, no notification is required if the only change is an addition or deletion within the list of waived tests, since these laboratories are authorized to perform any or all waived tests.

D. Notification Requirements for Laboratories with Certificate for Physician-Performed Microscopy (PPM) Procedures.--

1. Expansion to Include Tests Other Than Waived Tests or Examinations.--A laboratory with a certificate for PPM procedures may not perform any examination or procedure not specified as PPM procedures or approved as waived tests, until it has reapplied and HCFA has issued a registration certificate that covers the additional examinations or procedures requested by the laboratory.

2. Changes in PPM Procedures.--For a laboratory with a certificate for PPM procedures, no notification is required if the only change is an addition or deletion within the procedures specified as PPM procedures or approved as waived tests, since these laboratories are authorized to perform any or all PPM procedures and waived tests.

6268. FAILURE TO MEET PROFICIENCY TESTING REQUIREMENTS

Each laboratory (including laboratories licensed by States with approved laboratory licensure programs and laboratories holding a certificate of accreditation) is required to enroll and successfully participate in a HCFA-approved PT program for each of the specialties and subspecialties for which it is certified to test. While a laboratory is free to enroll in as many PT programs for each specialty and subspecialty as it wishes, it must designate a single PT program for each specialty, subspecialty and analyte or test which it will use to meet the PT requirements.

EXCEPTION: A laboratory that has been issued a certificate of waiver is not required to participate in PT and, therefore, does not have to meet the PT requirements.

A. Improper Referral of PT.--The RO may initiate an enforcement action when a laboratory has intentionally referred its PT samples to another laboratory for analysis and submits the other laboratory's results as its own. If it is determined that this has occurred, the SA must recommend that the laboratory's CLIA certificate be revoked for a minimum of one year. In addition, the SA recommends the imposition of a civil money penalty, as appropriate. Such occurrences may also warrant referral to OIG. The SA notifies the RO promptly if this is the case.

B. Failure to Successfully Participate in PT.--Laboratories which do not participate successfully in PT are subject to the same sanctions that are applicable for noncompliance with any other CLIA condition. Additionally, if any laboratory fails to participate successfully in PT, HCFA may require the laboratory to undertake training of its personnel or to obtain necessary technical assistance, or both, in lieu of, or in addition to, principal and alternative sanctions.

If a laboratory does not successfully participate in PT for a given specialty, subspecialty, analyte or test, the RO may impose one or more of the following to the RO:

- Personnel training and/or technical assistance;
- Alternative sanctions;
- Suspension or limitation of the laboratory's certificate; and/or
- Suspension of Medicare payment for the specialty or subspecialty for which the laboratory failed to participate successfully in PT.

If there is no immediate jeopardy, the RO generally selects personnel training and technical assistance for the first citation of unsuccessful PT participation in a specialty or subspecialty.

C. Failure to Successfully Participate in Gynecologic Cytology PT.--In gynecologic cytology, all individual cytotechnologists must participate in PT consisting of the review of unknown gynecologic cytology slides representing each of the response categories described at 42 CFR Part 493.945(b)(3)(ii)(A). The laboratory is required to ensure that each individual is tested at least once per year and obtains a passing score of at least 90%. If an individual fails the annual 10-slide gynecologic cytology PT, the laboratory must:

- Reschedule another 10 slide tests to be taken within 45 days after receipt of notification of failure;

- If the individual fails the second 10-slide retest, the SA schedules a 20-slide test to be taken within 45 days after receipt of notification of failure of the second 10-slide retest. The SA provides the individual with documented, remedial training and education in the area of failure. The SA assures that all gynecologic slides evaluated subsequent to the notice of failure of the retest are reexamined until the individual successfully participates in the 20-slide test. The SA documents slide reexamination; and

- If the individual fails the 20-slide retest, the SA ensures that the individual who failed the 20-slide retest stops examining gynecologic slide preparations immediately upon notification of failure. The individual may not examine cases until the laboratory ensures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, AND successfully participates in a 20-slide retest in cytology. The SA schedules another 20-slide test to be taken within 45 days after receipt of notification of failure.

If a laboratory fails to ensure that individuals performing gynecologic cytology are tested, or fails to ensure that individuals who fail a testing event are retested or subject to remedial action, as described in 42 CFR Part 493.855 (b), the SA recommends one or more of the following actions to the RO:

- Personnel training and technical assistance;

- Imposition of intermediate sanctions, including notification of laboratory clients under a directed PoC, as specified at §6276;

- Suspension of Medicare payments for gynecologic cytology; or

- Limitation of the laboratory's CLIA certificate to exclude gynecologic cytology.

D. Reinstatement After Failure to Successfully Participate in Proficiency Testing.--If a laboratory's certificate is suspended or limited or Medicare payments are suspended or Medicare approval is cancelled because of its failure to successfully participate in PT for one or more specialties, subspecialties, analytes or tests, or it voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, analyte, or test, the laboratory is required to demonstrate sustained satisfactory performance on two consecutive PT events, only one of which the SA may require to be on-site, before the laboratory may be considered eligible for reinstatement of its CLIA certification and Medicare approval in that specialty, subspecialty, analyte or test.

The cancellation period for Medicare approval or limitation or suspension period of its CLIA certificate for the failed specialty, subspecialty, analyte or test is a minimum of six months from the effective date of the adverse action. However, if the laboratory voluntarily withdraws its certification for the unsuccessfully performed PT, the six month period does not apply. The laboratory need only complete two consecutive PT events successfully.

If a laboratory's certificate is suspended or limited, if there is a suspension of all or part of Medicare payment, or Medicare and Medicaid approval is cancelled for gynecologic cytology, the laboratory must take corrective action and reapply to test in gynecologic cytology.

6270. ENFORCEMENT BASED ON ACTIONS OF LABORATORY'S OWNER, OPERATOR, OR EMPLOYEES

A. Enforcement.--

1. Basis for Action.--The RO may initiate an enforcement action when it finds that a laboratory's owner, operator(s), or one of its employees has:

- o Been found guilty of misrepresentation in obtaining a CLIA certificate;
- o Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;
- o Failed to comply with CLIA certificate requirements and performance standards;
- o Failed to comply with notification of change requirements;
- o Failed to comply with reasonable requests by the RO or HCFA's agent for any information or work on materials that the RO or HCFA's agent conclude is necessary to determine the laboratory's continued eligibility for its CLIA certificate or continued compliance with performance standards set by HCFA (no hearing necessary before the action);
- o Refused a reasonable request by the RO or HCFA's agent for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation (no hearing necessary before the action);
- o Violated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations;
- o Failed to comply with an alternative sanction previously imposed; or
- o Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all other laboratory's employees.)

2. Procedures.--If the RO determines that any of the above CLIA violations have occurred, the RO imposes a principal sanction. Also, the RO determines whether referral to OIG is necessary.

3. Referral to OIG.--In addition to imposing sanctions, the RO refers to OIG, within 30 days, for action any situation in which the RO determines:

- o The owner, operator, or one of the laboratory's employee is guilty of misrepresentation in obtaining a CLIA certificate;
- o The owner, operator, or one of the laboratory's employess performed or represented the laboratory as entitled to perform a laboratory examination or other testing not included in the laboratory's CLIA certificate;

o The owner, operator, or one of the laboratory's employess violated or aided and abetted in the violation of CLIA provisions; or

o The laboratory intentionally referred PT samples to another laboratory for analysis.

For these cases, see Exhibit 233 for a listing of the OIG field office addresses and the States for which they are responsible.

6272. SANCTION(S) - FACTORS CONSIDERED

A. Choice of Sanction.--HCFA is required to impose those sanctions that are most likely to bring laboratories into compliance in the shortest possible time from the date of determination of deficiencies. The RO considers a number of factors when choosing a sanction. These factors include, but are not limited to:

o Whether the deficiencies pose immediate jeopardy;

o The nature, incidence, severity, and duration of the deficiencies or noncompliance;

o Whether the same Condition-level deficiencies have been identified in three consecutive inspections;

o The accuracy and extent of the laboratory's records that address any remedial action taken to correct the noncompliance and their availability to the SA/RO;

o The relationship of one deficiency or group of deficiencies to other deficiencies;

o The overall compliance history of the laboratory, including any period of noncompliance that occurred between certifications of compliance;

o The corrective and long term compliance outcomes that would be achieved through application of the chosen sanction or sanctions;

o Whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies;

o The size and test volume of the laboratory;

o Any recommendation by the SA as to which sanction would be appropriate; and

o Whether the laboratory participates in the Medicare program, since additional sanctions might apply in these situations.

B. Number of Alternative Sanctions.--A separate sanction may be imposed for each Condition-level deficiency or a single sanction may be imposed for all Condition-level deficiencies that are interrelated and subject to correction by a single course of action.

C. Training and Technical Assistance.--This sanction option may be applied alone or with other sanctions when a laboratory is not in compliance with the CLIA PT requirements for successful participation.

6274. PRINCIPAL SANCTIONS

A. Suspension or Limitation of CLIA Certificate.--

1. Basic Rule.--The RO will not suspend or limit a CLIA certificate until after an ALJ hearing has upheld the suspension or limitation.

2. Exceptions.--The RO may suspend or limit a CLIA certificate before the ALJ hearing in any of the following circumstances:

- o The laboratory's deficiencies pose immediate jeopardy;
- o The laboratory has refused a reasonable request for information or work on materials that RO or HCFA's agent have concluded are necessary in determining compliance; or
- o The laboratory has refused to allow a survey of the laboratory or its operation.

B. Revocation of CLIA Certificate.--The RO will not revoke any type of CLIA certificate until after an ALJ hearing decision upholds the revocation. If the hearing decision upholds the revocation, it may be imposed even if HCFA had not previously limited or suspended the certificate.

6276. ALTERNATIVE SANCTION: DIRECTED PoC AND DIRECTED PORTION OF A PoC

A. Basis for Action.--The RO imposes a directed PoC for a laboratory that has Condition-level deficiencies. Under this sanction, the laboratory is directed to take specific corrective action within specific timeframes in order to compel the laboratory to achieve compliance. The laboratory must correct every deficiency addressed in the directed PoC. If the RO does not impose a directed PoC as an alternative sanction, it imposes at least a directed portion of a PoC when any of the following alternative sanctions are imposed:

- o State onsite monitoring;
- o Civil money penalty; or
- o Suspension of all or part of Medicare payments.

B. Processing Directed PoC.--When imposing this sanction, the RO takes the following actions:

1. Notice to Laboratory.--Gives the laboratory written notice of the proposed sanction, and an opportunity to respond within ten calendar days of this notice. (See Exhibit 234.)

2. Specific Corrective Action and Timeframes.--Directs the laboratory to take specific corrective action within specified timeframes.

3. Submission of Names of Laboratory Clients (Optional).--The RO may direct the laboratory to submit to the SA or another HCFA agent the names and addresses of its clients so they can be notified of sanctions being imposed and make decisions regarding retesting.

4. Duration and Effect of Sanction.--If a revisit or other written documentation confirms that the laboratory has not corrected its deficiencies within 12 months from the survey date, the RO cancels the laboratory's approval to receive Medicare payment for its services and notifies the laboratory of its intent to impose a principal sanction against its CLIA certificate. The directed PoC remains in effect until the effective date of the principal sanction against the laboratory's CLIA certificate.

C. Processing Directed Portion of PoC.--It may be necessary to notify clients, i.e., physicians, providers, and suppliers, and in some cases, individual patients, of a sanctioned laboratory, because of the seriousness of the noncompliance (e.g., immediate jeopardy) or for other reasons. In these cases, the RO directs the SA to notify the laboratory's clients. When the RO imposes this sanction, the following procedures apply:

o The RO directs the laboratory to submit to the SA, within 10 days after the date of its notice, a list of the names and addresses of all physicians, providers, suppliers, and other clients who have utilized some or all of the laboratory's services since the last survey or within any other timeframe the ROspecifies.

o Within 30 days of the date the SA receives this information, the RO may direct the SA to provide a notice to each of the laboratory's clients which contains the following:

- The name and address of the laboratory;
- The nature of the noncompliance; and
- The type and effective date of the alternative sanction or principal sanction.

The notice will also indicate that the client may contact the SA if additional information is needed. It is the SA's responsibility to obtain information or needed clarification in order to respond to clients' concerns about making an informed decision regarding patient notification and retesting or the use of another laboratory's services. If the RO determines that it is necessary to provide notice to each of the laboratory's clients, they will also arrange for a public notice to be published in the newspaper.

If the enforcement action is subsequently rescinded, the RO directs the SA to provide written notice of the action to the laboratory's clients and the newspaper within 30 days of the rescission.

If a principal sanction is imposed following imposition of an alternative sanction for which a listing of the laboratory's clients has already been obtained, the SA may use that same listing to notify the laboratory's clients of the imposition of the principal sanction.

6278. ALTERNATIVE SANCTION: STATE ONSITE MONITORING

A. Basis for Action.--Continuous or intermittent monitoring by the SA may be required to ensure the laboratory implements its PoC and complies with the Condition-level requirements. The monitor's responsibility is to oversee whether deficiencies are being corrected. The monitor has no management authority, i.e., the monitor cannot hire or fire staff, obligate funds, or otherwise dictate how the laboratory operates.

The laboratory must pay for the costs of onsite monitoring by the SA. The costs of onsite monitoring are computed by multiplying the number of hours of onsite monitoring in the laboratory by the hourly rate negotiated by the RO and each State. The hourly survey rate as negotiated during the budget process includes salary, fringe benefits, travel, and other direct and indirect costs negotiated by the RO and the State. Form HCFA-670 is used to collect this data.

B. Notice Requirement.--The RO provides written notice via overnight mail of the proposed sanction at least 15 days before the effective date of the sanction in no immediate jeopardy situations and at least five days notice when immediate jeopardy exists. In all cases, the laboratory is given ten days to respond (see Exhibit 235). The ten-day period to respond begins as soon as the notice of sanction is received by the laboratory.

C. Duration of Sanction.--Once imposed, onsite monitoring continues until the laboratory demonstrates that it is capable of ensuring compliance with all Condition-level requirements.

If a revisit or other written documentation confirms that the laboratory has not corrected its deficiencies within 12 months from the survey date, the RO cancels the laboratory's approval to receive Medicare payment for its services and the RO notifies the laboratory of its intent to impose a principal sanction against the laboratory's CLIA certificate. If the laboratory still does not correct its deficiencies, the Medicare sanction will continue until the principal sanction against the laboratory's CLIA certificate is effective.

6280. ALTERNATIVE SANCTION: CIVIL MONEY PENALTY

A. Scope and Basis.--Section 1846 of the Act and §353(h)(2)(B) of the PHSA authorizes the Secretary to impose civil money penalties on laboratories. Section 1846(b)(3) of the Act specifically provides that incrementally more severe fines may be imposed for repeated or uncorrected deficiencies.

When a laboratory has Condition-level deficiencies, the RO may impose a civil money penalty in lieu of, or in addition to, imposing a principal sanction against the laboratory's CLIA certificate, regardless of whether the deficiencies pose immediate jeopardy. According to the law, civil money penalties may only accrue and not be collected prior to a hearing (if one is requested). The penalty is collected according to the procedures outlined below.

B. Amount of Penalty.--The following factors are considered in determining the amount of penalty:

- The nature, scope, severity, and duration of the noncompliance;
- Whether the same Condition-level deficiencies have been identified during three consecutive surveys;
- The laboratory's overall compliance history, including, but not limited to, any period of noncompliance that occurred between certifications of compliance;
- The laboratory's intent or reason for noncompliance; and
- The accuracy and extent of laboratory records and their availability to RO or HCFA's agent.

C. Range of Penalty Amount.--

1. Immediate Jeopardy (Higher Range).--The penalty will range from $3,050 to $10,000 per day of noncompliance or per violation.

2. No Immediate Jeopardy (Lower Range).--The penalty will range from $50 to $3,000 per day of noncompliance or per violation.

3. Changes in Penalty Amount.--If a civil money penalty is proposed for immediate jeopardy and the immediate jeopardy is subsequently removed, but the Condition-level deficiency continues, the penalty amount may be shifted to the lower range.

In turn, if deficiencies cited during the survey did not pose immediate jeopardy and the RO proposed a penalty in the lower range, the RO may propose an increase in the penalty amount to the higher range when deficiencies become sufficiently serious to pose immediate jeopardy. In this case, propose the increase in penalty amount before the hearing.

D. Procedures.--

1. Notice of Intent.--The RO will notify the laboratory in writing via overnight mail of its intent to impose a civil money penalty at least 15 days before the effective date of the sanction in no immediate jeopardy situations and at least five days before the effective date when immediate jeopardy exists. The notice includes the following information (see Exhibit 235):

- o The statutory basis for the penalty;
- o The proposed daily or per violation amount of the penalty;
- o The factors considered in determining the penalty amount;
- o The laboratory's opportunity to respond within ten days of receipt of the notification, which includes the opportunity to submit additional information or a credible allegation of compliance; and
- o The laboratory's appeal rights, including the criterion that, if the laboratory does not request a hearing, RO may reduce the proposed penalty amount by 35 percent.

2. Accrual of Penalty.--The civil money penalty begins accruing five days after the date of the notice of intent if immediate jeopardy is cited. In no immediate jeopardy cases, the penalty begins accruing 15 days after the notice of intent.

3. Duration of Penalty.--The penalty continues to accrue until the earliest of the following occurs:

- o Condition-level compliance is verified, based on a revisit or evidence presented by the laboratory in its credible allegation of compliance. If a revisit finds compliance and the laboratory presents no credible evidence that compliance was achieved before the revisit, the civil money penalty stops accruing as of the last day of the revisit;
- o Credible evidence is presented by the laboratory at the time of the revisit which establishes that the laboratory achieved compliance with all Conditions before the revisit. In this instance, the civil money penalty stops accruing as of the date of compliance; or
- o The laboratory's CLIA certificate is suspended, limited, or revoked.

E. Computation and Notice of Total Penalty Amount.--After the laboratory's compliance is verified or its CLIA certificate has been suspended, limited, or revoked, the RO computes the total penalty amount due. This is after the 60-day period for requesting a hearing has expired without a request, the laboratory has waived its right to hearing, or the ALJ issues a hearing decision that upholds imposition of the penalty.

The RO sends a written notice to the laboratory informing it of the daily or per- violation penalty amount, the number of days or violations for which the penalty is imposed, the total amount due, and the due date for payment of the penalty. Payment is due 15 days from the date of the notice. At the RO's option, it may choose to approve a plan allowing the laboratory to pay the penalty, plus interest, over a period of up to one year from the original due date. The RO computes interest in accordance with 42 CFR Part 405.376(d).

F. Collection of Penalty Amounts.--The penalty amount due may be deducted from any monies then or later owed the laboratory by the Federal Government. Interest accrues on the unpaid balance of the penalty beginning on the due date, and is based on the rate specified in 42 CFR Part 405.376(d).

G. Settlement.--The RO has the authority to settle any case at any time before the ALJ issues a hearing decision.

6282. NONCOMPLIANCE WITH ONE OR MORE CONDITIONS - IMMEDIATE JEOPARDY EXISTS

When a laboratory's deficiencies pose immediate jeopardy, the RO requires the laboratory to take immediate action to remove the jeopardy. The RO initiates immediate action to suspend or limit the laboratory's CLIA certificate, and it may also impose one or more alternative sanctions as necessary to encourage compliance. If the RO has reason to believe that continuation of any activity by the laboratory (either by the entire laboratory operation or in any specialty or subspecialty of testing) would constitute a significant hazard to the public health, it may bring suit and seek a temporary injunction or restraining order against the continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has or whether it is a CLIA-exempt laboratory. The RO must notify the general public through the media and may also choose to notify the laboratory's clients.

In instances of immediate jeopardy, a suspension or limitation of the laboratory's CLIA certificate is not delayed because the laboratory has appealed and the hearing or hearing decision is pending. If the laboratory has not eliminated the immediate jeopardy, notify the laboratory that the RO will suspend or limit its CLIA certificate. The laboratory's CLIA certificate may be revoked following a hearing, when one is requested, if the ruling is in HCFA's favor.

A. Processing Immediate Jeopardy Enforcement Actions.--When immediate jeopardy is documented, the RO completes enforcement procedures within 23 calendar days. Processing days here are the maximum allowed. The RO does not postpone or stop the procedure unless the removal of the immediate jeopardy is achieved and verified.

1. Survey Date.--The survey date is the date on which the entire onsite survey process is completed.

2. Second Working Day.--No later than two working days following the survey date, the SA will telephone the RO to advise that they are certifying noncompliance and that immediate jeopardy exists.

3. Third Working Day.--No later than three working days following the survey date, the SA will:

o SA sends written notice, i.e., a warning letter (see Exhibit 113) to the laboratory (by overnight mail or facsimile) which includes the following:

- The Conditions out of compliance and their determination that these deficiencies constitute immediate jeopardy;

- The sanction or sanctions recommended. The sanction(s) must consist of at least suspension or limitation of the laboratory's CLIA certificate and may include one or more alternative sanctions. If the laboratory participates in Medicare, all (or, in the case of the limitation of a CLIA Certificate, part of) Medicare payments must be cancelled or suspended. If the laboratory unsuccessfully participated in PT, the training and technical assistance requirement may also be imposed. If a civil money penalty is recommended, the daily or per violation amount recommended must also be specified;

- The rationale for the proposed sanction(s);

- The projected effective date and duration of the proposed sanction(s);

- The authority for the proposed sanction(s);

- The time allowed (ten calendar days from the date of the notice) for the laboratory to respond to the notice, which includes the opportunity to submit additional information or a credible allegation of compliance to the RO (see Exhibit 235);

- The laboratory must pay the cost for any necessary revisits to verify compliance;

- The opportunity for the laboratory to notify the RO and/or the SA immediately if the jeopardy has been removed or the deficiencies have been corrected and there is evidence to support the allegation of compliance;

- The intent for the RO to publish a public notice in the local newspaper;

o SA should forward all supporting documentation to the RO by overnight mail; and

o The SA notifies the Medicaid agency of its certification of noncompliance, if the laboratory participates in the Medicaid program.

4. Eighteenth Calendar Day.--At least five days before the effective date of the sanction(s), the RO notifies the laboratory that the proposed sanction(s) will take effect and of its right to due process. In the notice, the RO acknowledges any evidence or information received from the laboratory. (See Exhibit 236.)

If the laboratory makes a credible allegation of compliance, the RO determines whether the SA can certify compliance on the basis of the evidence presented by the laboratory in its allegation, or if a revisit must be made to verify that the laboratory has, in fact, achieved compliance. (However, in situations of immediate jeopardy, an onsite revisit is usually necessary to determine first hand whether the jeopardy has been removed.) If the RO determines a revisit is needed, it instructs the SA to conduct it prior to the effective date of the sanction. The RO further instructs the SA to notify it of the outcome immediately upon completion of the revisit. The SA is not permitted to perform another revisit without permission from the RO.

If the RO concurs on the basis of evidence presented or the outcome of a revisit that the immediate jeopardy has been removed and there are no remaining Condition-level deficiencies, the RO certifies compliance and ensure that a CLIA certificate is issued or reissued to the laboratory, if appropriate. The RO advises the laboratory in writing that compliance has been achieved. If the immediate jeopardy has been removed, but Condition-level deficiencies remain, the RO uses the appropriate enforcement procedures.

If the laboratory fails to make a credible allegation of compliance, no revisit is necessary and enforcement procedures continue.

5. Twenty-Third Calendar Day.--If the laboratory is still out of compliance at the Condition-level and immediate jeopardy still exists, suspension or limitation of the laboratory's CLIA certificate takes effect. In addition, if the RO has reason to believe that the continuation of any activity by the laboratory (either the entire laboratory operation or any specialty or subspecialty of testing) would constitute a significant hazard to the public health, it may bring suit and seek a temporary injunction or restraining order against continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has and whether it is CLIA-exempt. If a principal sanction is imposed, the RO arranges to publish a public notice. In the public notice the RO states the type of adverse action, the reason for the adverse action, the effective date, and effect of the action. When a certificate is limited, the RO outlines in the public notice those specialties or subspecialties of tests that the laboratory is no longer authorized to perform and that are no longer covered under Medicare.

If the immediate jeopardy is subsequently removed, but Condition-level deficiencies still exist, the RO may continue to impose the principal sanction or any other alternative sanction until the laboratory achieves compliance.

6284. NONCOMPLIANCE WITH ONE OR MORE CONDITIONS - NO IMMEDIATE JEOPARDY

A. Procedures.--Enforcement procedures cannot exceed 12 months in cases where alternative sanctions are utilized. The RO or SA does not postpone or stop the procedure unless compliance is achieved and verified.

1. Survey Date.--This is the date on which the entire survey is completed.

2. Tenth Calendar Day.--No later than ten days following the survey date, the SA will notify the laboratory in writing by overnight mail or facsimile of the cited deficiencies, including Condition-level noncompliance (see Exhibit 112). The SA will inform the laboratory that the enforcement process provides the opportunity for correction and that, if compliance is achieved, the laboratory is to notify the SA immediately and furnish evidence to support its allegation. The SA will state that they will make a determination of compliance within 45 days of the survey, if an acceptable PoC and a credible allegation of compliance is received and verified.

3. Twentieth Calendar Day.--The laboratory must submit an acceptable PoC to the SA.

4. Forty-Fifth Calendar Day to the Fifty-Fifth Day.--If the laboratory has submitted an acceptable PoC and a credible allegation of compliance, the SA will determine whether compliance has been achieved. If compliance can be verified based on evidence presented by the laboratory, the SA will certify compliance, notify the laboratory, and transmit the certification information to the RO. If compliance cannot be verified based on the evidence presented, the SA will conduct a revisit.

If the laboratory fails to submit an acceptable PoC and a credible allegation of compliance, a revisit is not required. In these cases and those in which a revisit found continued noncompliance, the SA will prepare and send via overnight mail or facsimile a warning letter (see Exhibit 4-221) to the laboratory which includes the following information:

- The cited deficiencies, including the Condition-level noncompliance identified;
- The sanctions recommended for imposition against the laboratory. (If a principal sanction is not imposed an alternative sanction must be put in place.) If the laboratory unsuccessfully participated in PT, the training and technical assistance requirement may be imposed in lieu of any sanction or in addition to a sanction. If a civil money penalty is recommended, the daily or per violation amount recommended will be specified;
- The rationale for the proposed sanction(s);
- The projected effective date and duration of the proposed sanction(s);
- The authority for the proposed sanction(s);
- For alternative sanctions, the time allowed (ten calendar days from the date of the notice) for the laboratory to respond to the notice and the instruction for the laboratory to notify the SA if the deficiencies have been corrected and there is evidence to support the allegation. (See Exhibit 234);

- The fact that the laboratory must pay the cost for any revisit necessary to verify compliance;
- The sanction(s) which will take effect if compliance is not achieved; and
- The intent to publish a public notice in the local newspaper.

Subsequent SA revisits are subject to the RO's approval. Usually revisits occur between the first and 45th day and between the 45th and 90th day. If subsequent SA revisits are necessary they may be done with RO approval.

5. Sixtieth Calendar Day.--The SA will review any response received from the laboratory or from the revisit and determine whether compliance has been achieved. If compliance can be verified on the basis of evidence presented by the laboratory or from the revisit, the SA will certify compliance and transmit the information to the RO. If compliance cannot be verified on the basis of evidence submitted by the laboratory or from the revisit, the SA will certify noncompliance. They will also transmit the certification, supporting documentation and sanction recommendation to the RO. The SA will alert the State Medicaid agency, if the laboratory participates in Medicaid.

6. Seventieth Calendar Day.--If the RO's review concludes that the laboratory still has Condition-level deficiencies, it sends an official enforcement action notice to the laboratory which includes the following information (see Exhibit 236):

- The cited deficiencies, including the Condition-level noncompliance identified;
- The outcome of the RO's review of any evidence presented by the laboratory as the result of the SA's warning letter and/or any revisit conducted by the SA;
- The sanctions it will impose against the laboratory. If the laboratory unsuccessfully participated in PT, the training and technical assistance requirement may be imposed in lieu of any sanction or in addition to a sanction. If a civil money penalty is recommended, the daily or per violation amount recommended will be specified;
- The rationale for imposing the sanction(s);
- The projected effective date and duration of the sanction(s), and the effective date of the sanction(s) if Condition-level compliance is not achieved;
- The authority for imposing the sanction(s);
- The opportunity for the laboratory to notify the RO immediately if the Condition-level deficiencies have been corrected and there is evidence to support the allegation;
- The laboratory's responsibility for incurred cost for any revisit, to verify compliance;
- The laboratory's right to appeal; and
- The intent to publish a public notice in the local newspaper.

The newspaper notice must also explain that when the principal sanction of limitation is imposed, if the laboratory participates in Medicare, its Medicare participation will be affected. If the sanction of suspension of Medicare payment is recommended, the RO includes in the notice a statement asking the laboratory whether or not it intends to continue charging Medicare beneficiaries,

their private insurance, fiscal intermediary, or carrier for those specialties and subspecialties for which testing is being limited. The RO informs the laboratory that if it agrees not to charge its Medicare beneficiaries, their private insurance, fiscal intermediary, or carrier, it will have its payment for affected Medicare covered laboratory services suspended on the effective date of the sanction. The RO ensures that the laboratory understands that its Medicare approval will be cancelled, as opposed to being suspended, if it does not agree not to charge its Medicare beneficiaries, their private insurance, fiscal intermediary, or carrier. (The principal sanctions of suspension and revocation always result in a cancellation of Medicare participation.) The RO includes in the notice that if a response is not received by the RO within 15 days, it will be assumed that the laboratory does not agree not to charge for Medicare covered services and action will be taken to cancel Medicare payment on the effective date of the sanction. (See 42 CFR Part 493.1826(a)(ii).)

If the laboratory makes a credible allegation of compliance, the RO determines whether the SA can certify compliance on the basis of the evidence presented by the laboratory in its allegation or if a revisit must be made to verify that the laboratory has, in fact, achieved compliance. If the RO determines a revisit is needed, it instructs the SA to conduct it prior to the effective date of the sanction. The RO also, instructs the SA to notify it of the outcome immediately upon completion of the revisit.

If the RO concurs on the basis of evidence presented or the outcome of a revisit that there are no remaining Condition-level deficiencies, it certifies compliance and ensure that a CLIA certificate is issued or reissued to the laboratory, if appropriate. The RO advises the laboratory that compliance has been achieved.

If the laboratory fails to make a credible allegation of compliance, no revisit is necessary and enforcement procedures continue.

7. Ninetieth Calendar Day.--If compliance has not been achieved, the CLIA sanctions may take effect, however, the Medicare sanctions must take effect on the 90th day . If a principal sanction is imposed, the RO arranges to publish a public notice immediately. In the public notice, the RO states the type of adverse action, the reason for the adverse action, the effective date, and effect of the action. When a certificate is limited, the RO outlines in the public notice those specialties or subspecialties of tests that the laboratory is no longer authorized to perform and, therefore, are no longer approved for payment under Medicare.

a. Laboratory Participated in Medicare, Has Its Certificate Limited, and Does Not Agree Not to Charge Medicare Beneficiaries, Their Private Insurance, the Fiscal Intermediary (FI), or Carrier.--Payment for all Medicare-covered laboratory services is cancelled on the effective date of the sanction.

b. Laboratory Participated in Medicare, Has Its Certificate Limited, and Agrees Not to Charge Medicare Beneficiaries, Their Private Insurance, the FI, or Carrier.--

(1) Suspension of All Medicare Payment.--Payment for all Medicare covered laboratory services is suspended on the effective date of the sanction, if the laboratory agrees not to charge Medicare beneficiaries, their private insurance, the FI, or carrier for services for which Medicare payment is suspended, i.e., specialties, subspecialties out of compliance. The laboratory may choose to make this agreement in return for not having its Medicare approval cancelled immediately.

(2) Duration and Effect of Sanction.--The sanction remains in effect until the laboratory corrects all Condition-level deficiencies, but never beyond 12 months from the last date of the survey which identified the deficiencies.

If the laboratory corrects all Condition-level deficiencies and participates in Medicare, the RO resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected. If all deficiencies are not corrected by the end of the 12-month period specified above, the RO cancels the laboratory's approval to receive Medicare payment for its services. The RO may impose a principal sanction against the laboratory's CLIA certificate. The RO notifies the laboratory in writing via overnight mail or facsimile of the sanction and its right to due process. (See Exhibit 4-219)

NOTE: Due to the additional administrative process which requires a cytology contractor to send survey findings to the RO once the cytology survey is completed, the effective date of any adverse action imposed against a laboratory based on a cytology contractor's survey begins on the date the RO receives the official survey report.

6286. ENSURING TIMELY CORRECTION OF CONDITION-LEVEL DEFICIENCIES

A. Monitoring of Corrective Action(s).--The RO may direct the SA to revisit the laboratory or conduct a follow-up at any time to evaluate progress and at the end of the enforcement period to determine whether all corrections have been made.

B. Deficiencies Corrected Before Revisit.--If a laboratory produces credible evidence that it achieved compliance before the revisit, the RO lifts the sanctions as of that earlier date.

C. Alternative Sanction Imposed - Failure to Correct Condition-level Deficiencies.--If a revisit verifies that the laboratory has not corrected its Condition-level deficiencies within the period specified in the approved PoC, the RO initiates action to impose a principal sanction against the laboratory's CLIA certificate.

Alternative sanctions may continue for more than 12 months from the date of the survey while a hearing on the proposed principal sanction against the CLIA certificate is pending. If a hearing decision upholds the proposed principal sanction against the laboratory's CLIA certificate, the RO lifts the alternative sanction as of the day the principal sanction is effective.

D. Condition-level Deficiencies Corrected But Other Deficiencies Remain-12-Month Maximum for Correction.--At the end of the PoC period, if all Condition-level deficiencies have been corrected, but there are lower level deficiencies that remain uncorrected, the SA will request a revised PoC from the laboratory which addresses these remaining deficiencies. The SA will not accept a revised PoC which extends beyond 12 months from the date of the survey that originally identified the deficiencies.

If a revisit at the end of the 12-month period verifies that the laboratory has not corrected its deficiencies, the RO imposes a principal sanction against the laboratory's CLIA certificate and cancels the laboratory's Medicare approval.

Alternative sanctions may continue for more than 12 months from the date of the survey while a hearing on the proposed principal sanction against the CLIA certificate is pending and while Condition-level as well as lower-level deficiencies remain uncorrected. If a hearing decision upholds the proposed principal sanction against the laboratory's CLIA certificate, the RO lifts the alternative sanction as of the day the principal sanction is effective.

E. Revocation of CLIA Certificate.--If the RO decides to revoke a noncomplying laboratory's CLIA certificate, it may do so within the timeframes which the RO communicate to the laboratory in the notice of sanction if the laboratory does not request a hearing. If the laboratory requests a hearing, the CLIA certificate may not be revoked until the decision is rendered by the ALJ.

F. Acceleration of Timetable.--The RO switches from the no immediate jeopardy procedures to the accelerated procedures of §6284 at any point that it determines immediate jeopardy to patient health or safety exists.

6288. PROCEDURES FOR NONCOMPLIANT FEDERAL AND STATE OPERATED LABORATORIES

If the RO surveys a Federal or State operated laboratory and finds Condition-level noncompliance, one or more letters are sent to the laboratory including a warning and informing the laboratory of its opportunity to respond, its appeal rights, and the projected effective date of the sanction(s). (See Exhibit 4-218)

6290. PROCEDURES FOR LABORATORIES FOUND OUT OF COMPLIANCE DURING A SURVEY OF AN ACCREDITED LABORATORY

1. General.--The validation program is designed to evaluate the premise that a laboratory which receives accreditation is, in fact, meeting CLIA requirements. Validation surveys of accredited laboratories should be conducted in strict accordance with established procedures for SA certification surveys of nonaccredited laboratories to ensure a fair and consistent basis for evaluating the effectiveness of approved accreditation organizations.

In the case of a complaint against an accredited laboratory, the RO may choose to carry out its own investigation, or refer the complaint to the SA or accreditation organization, depending on the nature of the complaint. The RO reviews each complaint and determine whether a complaint investigation is warranted.

2. Laboratory Found Not in Compliance Following Validation Survey or Complaint Survey.--If deficiencies identified are Condition-level and pose immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public, the RO follows the adverse action procedures described in §6282 and notifies the laboratory by overnight mail or facsimile of the action being taken. (See Exhibit 237.)

If it is documented that the laboratory is out of compliance with one or more CLIA conditions, but the deficiencies do not pose immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the RO follows the adverse action procedures described in §6284. The RO processes the certification as any certification of a nonaccredited laboratory including the disclosure of survey findings and notifies the laboratory that it has been found out of compliance with a condition(s) and is, therefore, placed under SA jurisdiction. (See Exhibit 238.)

The laboratory is placed under the SA's jurisdiction until it reaches Condition-level compliance or when it loses its certificate of accreditation. For all cited Condition-level deficiencies, the RO informs the laboratory that a PoC must be obtained within 10 days of notification if participation in the CLIA program is to continue. (See Exhibit 238.)

Deficiencies identified on Form HCFA-2567 that are below Condition-level are referred to the applicable accrediting organization for follow-up. A PoC is encouraged for below Condition-level deficiencies, since the Form HCFA-2567 is a public record, but is not required.

A. Plan of Correction.--If the RO concurs with the SA's recommendation of an acceptable PoC, the RO sends written notification to the laboratory and to the accreditation organization. (See Exhibit 223.) Where the SA has found the PoC unacceptable and the RO concurs with the SA's recommendation, the RO notifies the laboratory accordingly and requests an amended acceptable PoC.

B. Compliance With All CLIA Conditions After Correction of Deficiencies.--When an accredited laboratory is determined to be in compliance with all CLIA conditions, the RO notifies the laboratory and the accrediting organization accordingly. (See Exhibit 224.) The RO informs the SA in writing to cease monitoring activities. Revisits are never authorized after an accredited laboratory has been notified that it is in Condition-level compliance with all CLIA conditions.

C. Notification of Accreditation Organization.--The RO will notify the Center for Laboratories at CO and the appropriate representative of the laboratory's accreditation organization within 60 days of completion of the survey when the laboratory is placed under your monitoring jurisdiction. The RO copies all written communication to CO and the accreditation organization. The laboratory continues to be accredited. However, it is subject to the same requirements, survey, and enforcement procedures applied to nonaccredited laboratories found out of compliance following a survey. The facility is monitored until it reaches Condition-level compliance or when its certificate of accreditation is revoked.

6292. DEFICIENCIES THAT ARE NOT AT CONDITION LEVEL

If a laboratory has deficiencies that are not at the Condition level, the following rules apply.

A. Initial Action.--The laboratory must submit a PoC that is acceptable in terms of both its contents and the timeframes for correction.

For the PoC to be acceptable, it must show that the laboratory can achieve compliance and that compliance can be verified within 12 months from the survey date.

If a laboratory fails to submit an acceptable PoC, and subsequent requests for an acceptable PoC are unsuccessful, the RO may cancel the laboratory's approval to receive Medicare payment for its services in accordance with 42 CFR Part 493.1842(a)(2)(ii). In addition, the RO may consider the laboratory's failure to comply with reasonable requests for information for purposes of 42 CFR 493.1840(a)(4) and may initiate a principal sanction, i.e., suspension, limitation, revocation of the CLIA certificate, on the basis of this failure.

B. Ensuring Timely Corrections.--If the laboratory has not corrected its deficiencies within 12 months after the last date of the survey which identified the deficiencies, the RO cancels the laboratory's approval to receive Medicare payment for its services and impose a principal sanction against the laboratory's CLIA certificate.

6293. INTERVENING ACTIONS THAT DO NOT POSTPONE OR DELAY ENFORCEMENT TIMETABLE

A. Credible Allegation of Compliance.--A credible allegation is a statement or documentation that:

- Is made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- Is realistic in terms of the possibility of the corrective action being accomplished between the last day of the survey and the date of the allegation; and
- Indicates resolution of the problems.

Only correction of noncompliance can stop an enforcement action.

B. Change of Ownership.--A change of ownership does not affect completion of an enforcement action. However the RO or SA does not solicit a PoC from the new owner. Court-appointed receivership is not a basis for cessation of the sanction process. Following revocation, the new owner may, however, request approval for participation as a new CLIA laboratory. The SA requests that the new owner complete a new Form HCFA-855 in accordance with the procedures described in §2710. The SA or RO may also request, as appropriate, a new Form HCFA-116. The provision at 42 CFR Part 493.1840(a)(8) only applies to a prior laboratory, which the new owner may have owned, not the laboratory he/she is taking over in this case.

6294. DURATION OF ALTERNATIVE SANCTIONS

An alternative sanction continues until the earlier of the following occurs:

- The laboratory corrects all Condition-level deficiencies; or
- A principal sanction against the laboratory's CLIA certificate becomes effective.

If an alternative sanction is imposed for Condition-level noncompliance which does not pose immediate jeopardy, and a revisit verifies that the laboratory has not corrected all deficiencies within 12 months from the survey date, the RO takes the following action:

- Cancels the laboratory's approval to receive Medicare payment for its services, and discontinues any Medicare alternative sanctions as of the date the cancellation is effective;
- Notifies the laboratory of its intent to impose a principal sanction against the laboratory's CLIA certificate and of its right to a hearing; and
- Imposes (or continue to impose) any alternative sanctions that do not pertain to Medicare payments. Sanctions imposed against the CLIA certificate may continue for more than 12 months from the date of survey while a hearing on the proposed limitation, suspension, or revocation of the laboratory's CLIA certificate is pending.

6295. LIFTING OF ALTERNATIVE SANCTIONS

A. General Rule.--Alternative sanctions are not lifted until compliance with all Condition-level requirements is verified.

B. Credible Allegation of Compliance.--When a sanctioned laboratory submits a credible allegation of compliance, the RO determines whether:

- Compliance can be verified on the basis of evidence submitted by the laboratory in its allegation or other written documentation; or
- A revisit is necessary to verify whether compliance has been achieved.

If compliance can be verified on the basis of evidence submitted, the RO lifts the sanction as of the date of compliance supported by the evidence.

C. Compliance Achieved Before or During Date of Revisit.--If a laboratory is in compliance at the time of the revisit and it produces credible evidence that it achieved compliance before the revisit, the RO lifts the sanction as of that earlier date. If the revisit finds compliance and there is no credible evidence presented by the laboratory that compliance was achieved before the revisit, the RO lifts the sanction as of the last day of the revisit.

6296. SANCTION IMPOSED ON ANY TYPE OF CLIA CERTIFICATE-EFFECT ON MEDICARE APPROVAL

A. Suspension or Revocation of Any Type of CLIA Certificate.--When the RO suspend or revoke any type of CLIA certificate, the laboratory's approval to receive Medicare payment for its services is cancelled concurrently.

B. Limitation of Any Type of CLIA Certificate.--When the RO limits any type of CLIA certificate, it concurrently cancels the laboratory's approval to receive Medicare payment to only those specialties or subspecialties that are authorized by the laboratory's limited certificate.

6297. SUMMARY OF RO RESPONSIBILITIES DURING CLIA ADVERSE ACTION PROCESS

During an adverse action or civil suit against a laboratory, the RO has the following responsibilities:

- Notifies the laboratory of the exact enforcement action to be imposed against it, the authority for the action, and the effective dates;
- Generates revised CLIA certificates, if necessary;
- Suspends or limits CLIA certificate if a laboratory's noncompliance poses immediate jeopardy;
- Assists in the collection of evidence and other information related to criminal actions by the laboratories; and
- Notifies carriers and fiscal intermediaries of Medicare payment sanctions imposed against laboratories.

6298. LIMITATION ON MEDICAID PAYMENT

As provided in §1902(a)(9)(C) of the Act, payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that meets CLIA requirements.

6299. CLIA VIOLATIONS - OIG EXCLUDES LABORATORY FROM MEDICARE PARTICIPATION-EFFECT ON CLIA CERTIFICATE

If OIG excludes a laboratory from participation in the Medicare program, the RO suspends the laboratory's CLIA certificate for the period during which the laboratory is excluded.

The notice of suspension should be sent immediately after the RO learns that the exclusion takes effect. The laboratory is entitled to a hearing before the suspension is imposed, but may only appeal whether the OIG exclusion did take effect. A change of laboratory ownership may not release a laboratory from its exclusion from Medicare and the suspension.

Appeals of Adverse Actions

6300. APPLICATION OF APPEALS PROCEDURES

The procedures under the CLIA program for reconsiderations, hearings and appeals, and civil actions outlined in this section apply to all laboratories that meet the definition for a laboratory under CLIA and, where indicated, prospective laboratories. Since CLIA mandates that virtually every laboratory is subject to CLIA requirements, and Medicare and CLIA conditions for laboratories are now consolidated, there is one set of procedures for all appeal actions by laboratories. These procedures are set forth in 42 CFR Part 493.1844 and are explained in the following sections.

6302. RECONSIDERATION

A. Definition of Reconsideration.-- Thorough, independent review by HCFA of a prior decision by HCFA. The entire body of evidence, including any new information presented is reviewed.

B. Right to Reconsideration.-- A reconsideration may be given only to a prospective laboratory (i.e., a laboratory which is applying for a CLIA certificate or for both a CLIA certificate and approval to receive Medicare/Medicaid payment for its services) or to a laboratory which applies to test in new specialties or subspecialties. The RO reconsiders only initial determinations as outlined below and in 42 CFR Part 493.1844(b). (Appeals of initial determinations of laboratories that already hold a CLIA certificate and/or have previously been approved to participate in Medicare/Medicaid are submitted directly to an ALJ. There is no reconsideration given at RO level for these types of cases.) The following are the initial determinations applicable to prospective laboratories, and, therefore, are valid reasons for which prospective laboratories may provide the SA (or the RO directly) with a written request for a reconsideration:

- o The denial of a laboratory's request for a CLIA certificate;
- o The denial of a laboratory's request for additional specialties or subspecialties; and
- o The denial of a laboratory's request for approval to receive Medicare payment for its services.

In 42 CFR Part 493.1844(c), there is a list of administrative actions that are not initial determinations and are, therefore, not appealable and not subject to a reconsideration (see Exhibit 4-226).

C. Request for Reconsideration: Manner and Timing.--A request for reconsideration is any written expression of dissatisfaction with the RO's initial determination with regard to a CLIA certificate. The request may be in the form of a letter, statement, or submittal of a new request for Medicare approval or a CLIA certificate, must be submitted within 60 days of the initial determination, and must include a statement of the issues with which the prospective laboratory disagrees, with the reasons for the disagreement.

D. Actions Upon Receipt of Request for Reconsideration.--The RO or the SA will date-stamp the request when it is received, and promptly acknowledge the request. A copy of the request and the letter of acknowledgement will be forwarded immediately to the RO from the SA. Any additional information the SA subsequently receives from the prospective laboratory that may affect the reconsideration or hearing will be forwarded to the RO. All reports of onsite visits and telephone contact with the prospective laboratory will also be sent to the RO from the SA.

E. Withdrawal Requests and Extensions.--If the affected party files a written notice to withdraw its request for reconsideration, the RO will approve the withdrawal request if it is received prior to its mailing the notice of reconsidered determination.

If the prospective laboratory is unable to file a request for reconsideration within 60 days, it may file a written request for an extension to the RO, stating the reasons why the request was not filed timely. The RO is responsible for deciding whether good cause for missing the filing deadline existed. If the affected party has not shown good cause for the late filing, the RO should dismiss the reconsideration request. It may also dismiss a request for reconsideration from a prospective laboratory if it does not involve an initial determination, as defined in 42 CFR Part 498.3.

6304. RO NOTICE OF RECONSIDERED DETERMINATION

A. Determination Reversal (Approval).--If a reconsideration is requested and a laboratory's application is subsequently approved, the RO confirms compliance within 20 days of approving the prospective laboratory's application to participate in the CLIA program. After confirming that the Form HCFA-116 is correct, the RO has a CLIA ID number assigned and completes the applicable portions of the Form HCFA-1539. The RO marks on the Form HCFA-1539 and Form HCFA-116 "Determination Reversed." The RO issues and bills the laboratory for a registration certificate, certificate of waiver, or certificate for PPM testing, whichever is applicable.

B. Denial Affirmed.--The RO includes with the notice of this decision a listing of each statutory and regulatory requirement with which the prospective laboratory is not in compliance and why.

C. Initial Denial NOT Signed by ARA.--If the ARA did not sign the initial denial notice, he or she should sign the reconsidered denial notice.

D. Initial Denial Signed by ARA.--If the ARA signed the original notification of denial, he/she forwards the file and formal recommendation to the Deputy RA or RA. The notice of reconsideration and denial of the initial determination will be released via the signature of the RA. The RO mails the action, notifies all affected components, and transmits the Form HCFA-1539 and Form HCFA-116.

E. Administrative Evidentiary Hearing.--Any prospective laboratory dissatisfied with a reconsidered determination under 42 CFR Part 493.1844(e)(1) or a revised reconsidered determination under 42 Part CFR 498.30 may submit a written request for an administrative evidentiary hearing by the Departmental Appeals Board (DAB).

6306. ADMINISTRATIVE HEARING

A. Actions Which Are Appealable.--The following actions are initial determinations and are, therefore, subject to appeal in accordance with 42 CFR Part 493.1844:

- The suspension, limitation, or revocation of the laboratory's CLIA certificate because of noncompliance with CLIA requirements;
- Denial of a CLIA certificate;
- The imposition of alternative sanctions under 42 CFR 493.1806 through 1807 (but not the determination as to which alternative sanction(s) to impose); and
- Denial or the cancellation of the laboratory's approval to receive Medicare payment for its services.

B. Procedure for Requesting a Hearing.--Any laboratory or prospective laboratory dissatisfied with a request of reconsideration of an initial determination is entitled to an administrative hearing before an ALJ of the DAB. If the affected laboratory shows good cause why the request for a formal hearing was not filed timely, the ALJ is responsible for granting the filing extension. However, a prospective laboratory must go through the reconsideration process first before filing a formal appeal.

Whereas, any laboratory, which already holds a CLIA certificate and/or participates in Medicare/Medicaid, that is dissatisfied with any of the initial determinations listed above would file its appeal directly with an ALJ of the DAB. Previously approved laboratories are not given reconsideration determinations. Hearings are conducted in accordance with Subpart D of 42 CFR Part 498. In order to request a hearing, the laboratory, prospective laboratory or its legal representative must file a written request for an appeal with the SA or the RO within 60 days of its receipt of the notice of initial, reconsidered, or revised determination.

C. Content of the Request for Hearing.--The request for a hearing must contain the following information:

- Specific issues or findings with which the laboratory disagrees; and
- Specification of the basis for contending that your findings, or the RO's, are incorrect.

D. Relationship of Action on Laboratory's CLIA Certificate to Timing of Hearing.--In cases where a laboratory's deficiencies do not constitute immediate jeopardy action against a laboratory's CLIA certificate occurs after the administrative hearing if one is requested. In cases of immediate jeopardy, a CLIA certificate may be suspended or limited prior to an ALJ hearing. Civil money penalties, which accrue during periods of noncompliance prior to the hearing, are collected following a hearing decision favorable to HCFA. Intermediate sanctions other than civil money penalties and cancellation of the laboratory's Medicare/Medicaid approval may be imposed prior to an ALJ hearing. If a laboratory's CLIA certificate is due to expire prior to the hearing date, HCFA will reissue it for a 2-year period, in order for the laboratory to remain operational. (See Exhibit 4-225.)

6308. PROCESSING OF HEARING REQUESTS

Any laboratory or prospective laboratory dissatisfied with an initial, reconsidered or revised determination may file a written request for an administrative hearing before an ALJ. This request must be filed within 60 days of the laboratory's receipt of the notice of the sanction. The RO sends all hearing requests that are sent to it (or which are sent to the State and forwarded to the RO) to:

Departmental Appeals Board
Civil Remedies Division
Room 637-D, HHH Bldg.
200 Independence Avenue, SW
Washington, D.C. 20201.

The telephone number is (202) 690-5863. The DAB will inform the RO once a hearing date is set so that the RO may inform the laboratory.

If the laboratory requests a hearing prior to receiving a notice of sanction or a notice of a reconsidered determination, the RO explains in writing to the laboratory why the request for an appeal is premature and provides instructions to the laboratory or prospective laboratory explaining the procedures for correctly filing the appeal.

6310. SCHEDULING OF THE HEARING

A. Timing of the Hearing.--Any laboratory, regardless of whether it is approved under Medicare, will receive one administrative evidentiary hearing by the DAB. The Medicare principal sanction (cancellation of Medicare approval) may take place prior to the hearing, while the principal sanctions authorized under CLIA are imposed after the hearing, unless immediate jeopardy exists.

B. Relationship of Cancellation of Medicare Approval to the Timing of the Hearing.--If a laboratory does not correct its Condition-level noncompliance within 12 months from the date of the survey which identified the noncompliance, approval for Medicare payment for its services may be cancelled at any time during those 12 months. Since laboratories receiving Medicaid payments in each State must be Medicare-approved, Medicaid payments under the State plan may not be made to those laboratories for which Medicare approval has been cancelled. Subsequent to Medicare cancellation, the administrative hearing (if one had been requested by the laboratory within the appropriate timeframe) is held.

C. Relationship of Action on a Laboratory's CLIA Certificate to the Timing of the Hearing.--In cases where a laboratory's deficiencies do not constitute immediate jeopardy, action against a laboratory's CLIA certificate occurs after the hearing. Civil money penalties, which accrue during periods of noncompliance prior to the hearing, are collected following the hearing decision.

6312. ADVERSARIAL HEARINGS DECISIONS BY ALJ

Any laboratory or prospective laboratory dissatisfied with the ALJ/DAB's decision may, within 60 days from the receipt of the notice of the ALJ's decision, file a written request for review in accordance with Subpart E of 42 CFR Part 498. The authority to change a decision rests solely with the DAB. If the request is received by the SA, it transmits the request immediately to the RO. The RO will keep the SA apprised of action on such cases.

NOTE: CMP and principle sanctions can go to the U.S. Court of Appeals of the Circuit in which the laboratory has its principal place of business, a petition for judicial review (Part 493.1846(f)(3)).

6314. READMISSION TO CLIA PROGRAM

If an administrative hearing decision upholds HCFA's determination to revoke a laboratory's CLIA certificate, the owner and operator of the laboratory may not own or operate a laboratory for two years, as outlined in 42 CFR Part 493.1840(a)(8). If the laboratory is taken over by another owner and/or operator who does not meet the criteria in 42 CFR 493.1840(a)(8), the laboratory must submit another CLIA application according to the procedures outlined in 42 CFR 493.45.

6316. LABORATORY REGISTRY

The CLIA statute and 42 CFR Part 493.1850 require HCFA to make information available to physicians and to the general public that is useful in evaluating the performance of laboratories. The laboratory registry is compiled for the calendar year preceding the date the information is made available, includes appropriate explanatory information to aid in the interpretation of the data, and is published in the Federal Register. The categories included in the registry are:

- A list of laboratories that have been convicted under Federal or State laws relating to fraud and abuse, false billing or kickbacks;

- A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reason for the adverse actions;

- A list of persons who have been convicted of violating CLIA requirements, as specified in §353(1) of the PHSA, together with the circumstances of each case and the penalties imposed;

- A list of laboratories on which alternative sanctions have been imposed, showing: (1) the effective date of the sanctions; (2) the reasons for imposing them; (3) corrective action taken by the laboratory; and (4) if the laboratory has achieved compliance, the verified date of compliance;

- A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation;

- All appeals and hearing decisions;

- A list of laboratories against which HCFA has brought suit under 42 CFR Part 493.1846 and the reasons for the actions; and

- A list of laboratories that have been excluded from participation in Medicare and Medicaid and the reasons for the exclusion.

NOTE: Actions under appeal are noted as such.

It is recommended that the RO assemble the information for the registry on an ongoing basis in order to facilitate its compilation. Although significant elements of the registry will be provided by OIG, the data relating to the imposition of CLIA sanctions, subsequent corrective actions, and hearing and appeals decisions will be most readily available to the RO. In reporting its region's listing, the RO should use the following format:

- Name, address, and CLIA ID number of laboratory;
- Sanction(s);
- Date of sanction(s);
- Reason for sanction(s); and
- Current status.

A laboratory should only be listed in the registry when an action has been completed that meets one of the above designated categories. A single determination may include several distinct sanctions, and each CLIA sanction may be appealed to the Departmental Appeals Board.

Budget and Administration

6400. THE CLIA FEDERAL/STATE RELATIONSHIP

The Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578) continue to foster a close and integrated relationship between the Federal government and SAs charged with the implementation, maintenance and enforcement of Federal requirements. Regulations and guidelines developed are the interpretative documentation that both State and Federal agencies will follow as we jointly seek to assure that the clinical laboratory improvements mandated by Congress are initiated properly and fulfilled in the most effective manner possible.

The SA is the key local interface and representative of HCFA with the clinical laboratories that are not State or Federally owned. Although CLIA has expanded the Federal government's oversight role to virtually all laboratories in the country that do testing for diagnostic purposes, it is through the SAs or their agents that virtually all non-Federal CLIA oversight of laboratories occurs. SAs or their agents are responsible for hiring, training and managing personnel needed to fully implement and assure the ongoing effective conduct of regulations promulgated for CLIA in accordance with contractual provisions in the 1864 Agreement.

The law further mandates that CLIA be a self-funded program. Fees for compliance determination and oversight covering all CLIA-related expenses must be established and collected. There are no other funds available from any source other than from those laboratories subject to CLIA requirements. Therefore, for CLIA laboratories, workload planning and budgeting are key features in the CLIA Federal/State administrative partnership. This is a negotiated process which closely involves the SA, each State's budget process, the laboratory surveys and related workloads and the cost to accomplish the required workload. The SA is the responsible State organization in this process. The RO is the Federal government's representative for helping the States develop acceptable work plans and appropriate budgets to accomplish the required workload targets. For CLIA-exempt and accredited laboratories, payment of the initial fees and fees covering the Federal oversight activities constitutes the main exchange between the State and HCFA in the budget process. Additional charges may be made to individual laboratories by the CLIA exempt State or accrediting body.

The budget process begins with the State preparation of the Planned Workload Report (with its narrative activity work plan) and a Budget Request that is forwarded to HCFA. Next comes budget approval and the advancement of CLIA funds. Survey Team Composition and Workload Reports are prepared and submitted for each completed survey and related support activity, and quarterly reports of work completed are filed for Federal payment for SA completed work on the CLIA workload.

6402. FEDERAL ADMINISTRATIVE RESPONSIBILITIES

Among the responsibilities of the parties are obligations imposed upon the Federal government. The following are delegated to the ARA, HSQ:

- Setting policy and policy interpretations;
- Providing consultation to necessary agencies involved in administering the Federal requirements;
- Paying the appropriate and allowable costs of the SA functions relating to the administration of regulations and guidelines for CLIA;

o Making determinations of allowable State costs submitted for Federal payment; and

o Controlling payment of funds to appropriate State agencies for costs incurred in administering CLIA.

6404. NATURE AND SOURCE OF PAYMENTS TO STATES

A. Funds for Clinical Laboratory Improvement Act Related Activities.--The Clinical Laboratory Improvement Amendments of 1988 mandates that the CLIA program be self-funded. Program participants (laboratories that do clinical testing of human specimens for diagnostic purposes) bear all financial burden for implementation, day-to-day operations, enforcement and other Federal/State oversight expenses of the program. The funds needed to run the program come from the variety of mechanisms put in place to administer the program. The sources include:

o Registration Certificate fees, from the start-up period, that are to accompany the initial registration;

o Certificate fees for Federal administration of the program; and

o Compliance determination and enforcement fees to cover the costs incurred by the State and Federal government to ensure program requirements are met.

B. Laboratory Remitted Funds.--When these laboratory-remitted funds are received by a lock-box contractor, they are deposited into a HCFA CLIA account where they are available for State advances and payments for CLIA work. The States bill HCFA for payment for surveys, visits or re-contacts, complaint visits, follow-ups and other CLIA work, by preparing a Form HCFA-670 , Survey Team Composition and Workload Report (Exhibit 74) and a Form HCFA-102, Budget/Expenditure Report (Exhibit 116). The Form HCFA-670 for CLIA is intended to capture the total time expended on a laboratory survey, or other CLIA-related workload from beginning to end. All work performed, including all discussions, report preparation and similarly related work expenditures for all employees involved in the process are to be reported. Payments to States under §1864 of the Act are made from user fees collected from the laboratories at registration. These fees pay for administrative expenses (including advances or payment to States under §l864) as authorized for expenditure from the CLIA user fee account.

As surveys and related CLIA work are performed, actual expenditures are determined and forwarded to the RO for review and action. They are then forwarded to HCFA's CO or their representative for approval. An end of year reconciliation and balancing of accounts will occur between HCFA and each State. Actual expenses data will then be used by HCFA as a basis for determining and setting future fee schedules for the participating laboratories.

6406. STATE AGENCY ADMINISTRATIVE RESPONSIBILITIES

The SA is responsible for:

o Establishing and maintaining organizational relationships with other State and local governmental groups, as necessary, for attaining program or related program goals;

o Knowing the needs of laboratories in the State which affect their ability to comply with program standards, and devising and executing plans to address those needs;

o Advising the RO of program needs and trends, and of responsive actions which have been taken;

o Providing the material, equipment, and the training and support of personnel to perform the above functions; and

o Furnishing necessary records and accounting to justify costs claimed for payment by HCFA.

6408. STATE AGENCY RESPONSIBILITY FOR RECORDS AND REPORTS

SAs are to establish and maintain basic records and prepare operating reports in the form of the Form HCFA-670, Survey Team Composition and Workload Report, (Exhibit 74), and the Form HCFA-103, Quarterly Expenditure Report, (Exhibit 117). These report the essential administrative and fiscal information, records and reports which will help to provide an:

o Evaluation of the effectiveness of program operations;

o Analysis of workloads and degree of accomplishment;

o Identification of administrative or technical problem areas;

o Development and justification of payments; and

o Documentation to support the expenditure of CLIA funds for compliance determination surveys and oversight activities.

SAs are responsible for maintaining records and reports, on a continuing or special request basis, which are pertinent to the managing of agency operations and reflect the agency's workload. Records and reports are to be designed to fit within the framework of the SA operations. The design of those records and report mechanisms need not be limited to paper applications; it is acceptable for all parties to strive to use good modern management practices and tools to support the CLIA effort. Computer formats of HCFA forms and reports are being developed and encouraged. Where possible, the use of automation to streamline reporting and data compilation is encouraged. The HCFA requirement for a minimum of specific records and reports is not intended to limit in any way SAs fiscal and administrative practices. Reasonable costs to facilitate the implementation of quality modern data bases and information systems are to be available for CLIA funding. However, if a State's fiscal and administrative requirements are in excess of the CLIA-mandated requirements, then expenses for work done above and beyond that prescribed by CLIA is not normally to be borne by the laboratories nor the CLIA program. However, the State has the authority to charge those laboratories in their CLIA-exempt program according to any fee schedule they determine is appropriate. Federal surveys of a sample of the CLIA-exempt laboratories will be billed according to the Federal fee schedule in 42 CFR Part 493.638ff. SAs will not be paid for work done in excess of that prescribed by CLIA 88.

6410. STATE AGENCY RESPONSIBILITY FOR STAFF TRAINING AND DEVELOPMENT

A. Staff Training.--The SA is responsible for providing continuing education to employees. In conjunction with, and subject to, the approval of the Regional Training Administrator (RTA), SAs must have a procedure for identifying the training needs of the surveyors. That procedure must insure that SOM revisions, RO instructional letters, and the results of regular and Federal Monitoring Surveys (FMS) are included in the training agenda. Training may be provided in a variety of forms: in-service training; formal education; State, regional or national conferences; seminars or workshops. Costs for all courses and training must be within approved fiscal limitations.

B. In-Agency Training.--The SA must have its own program of staff development which responds to the needs of new employees for orientation and basic training, and to the needs of experienced employees for continuing development and education.

C. Outside-of-Agency Training.--In evaluating the appropriateness of any outside training activity for CLIA funding, SAs and the RO must consider the degree to which the trainees will benefit when carrying out the CLIA survey and certification program.

6412. ROLE OF THE HCFA RO WITH STATE AGENCY PROGRAM ADMINISTRATION

The RO is the HCFA representative at the regional level for all CLIA survey and certification functions. The RO is responsible for:

- o Reviewing and recommending action on each budget submittal;
- o Furnishing program guidance and policy interpretation;
- o Coordinating communications with the SA representatives, accredited providers, and laboratories on CLIA survey and certification activities; and
- o Consulting on a regular basis with the SA, contractors or representatives for mutual assessment of program activities, achieving stated objectives, and establishing future goals.

Before approving each State budget submittal, the RO evaluates all information available and determines answers to the following questions:

- o Is the plan of program activities appropriate to national CLIA annual and biennial goals?
- o Do the workload and activity plans and staffing estimates properly place emphasis on fulfilling program goals?
- o Does the budget request represent a consistent application and understanding of approved principles of reasonable cost to the SA's specific circumstances?

6414. CLIA BUDGET - RO PROCEDURES

A. General.--CLIA is a self-operated program. Fees from compliance determination and oversight covering all CLIA-related expense must be established and collected. There are no other funds available from any source to administer the program other than from those laboratories subject to CLIA requirements.

B. Regional Administrative Responsibilities.--The ROs have the primary responsibility for the efficient and effective administration of the CLIA program in the States in their respective regions. It is the RO's responsibility to:

- o Issue the budget call letter to each State;
- o Furnish the SA with administrative, budget and program guidance, policy interpretation, and leadership;
- o Review, negotiate, and recommend action on each SA budget and subsequent quarterly expenditure reports;
- o Coordinate communications relating to CLIA between the SAs and other HCFA components;
- o Consult with SAs to develop mutual agreement on the conduct of program activities, the achievement of stated objectives, and the establishment of future goals;

- Make determinations of allowable State costs submitted for Federal payment; and
- Control payment of funds to SA for costs incurred in administering CLIA.

Before approving each State budget submittal, the RO considers the following questions:

- How does the plan of program activities appropriately address the pertinent priorities and program emphases?
- Does the workload activity plan and the staffing estimate reflect the proper emphasis needed to fulfill the priorities listed in the budget call letter?
- Have the RO approved all appropriate reasonable costs that are peculiar to each SA's specific circumstances? If not, has the RO communicated this and a proper explanation to all concerned parties?
- Do all approved SA budgets reflect a consistent application and understanding of the programmatic, administrative, and fiscal principles and guidelines set forth in the SOM and the budget call letter?

6416. BUDGET CALL - RO PROCEDURES

Each fiscal year (usually the February or March preceding the new fiscal year) CO issues a budget call letter. This letter serves as official notification to begin the budget process with each State for the coming fiscal year. The call letter provides national program emphasis including the workloads to be accomplished during the next fiscal year and should be adhered to closely.

Upon receipt of the budget call letter, the RO prepares State call letters to inform the States of the national and regional goals and priorities for CLIA. Upon receipt of each State's proposed budget, The RO records the date received. This is the actual beginning of the negotiated budget process between the SAs and your office.

Each budget submission requires close attention and proper scrutiny. It is imperative that the RO manage the SA's CLIA activity, including budgets, aggressively for efficiency and productivity. Contracts and purchases planned by the SAs and approved by the RO, especially large purchases of computer hardware and software, must be guided by the latest Office of Management and Budget (OMB) circulars and HCFA standards, policies, and guidelines. It is imperative that costs be contained and appropriately managed. Therefore, when the RO encounters any unusual plans or purchases, it assures that they are supported by adequate written justification and that the RO is convinced of the actual need to support efficiency and productivity.

It is important that the RO question and challenge unsupported spending levels, or supported requests that the RO does not feel are needed or the program cannot afford. Aggressive monitoring throughout the year can help to lower the cost of managing the CLIA program. Questions or problems the RO has regarding State budgets may be directed to the CO budget staff.

It is important that CLIA budget requests, funding requirements and expenditure reports be submitted separate from those for the Medicare and Medicaid programs. CLIA specific forms have been developed and must be used for CLIA program expenditures.

6418. REGIONAL ALLOCATIONS

The allocation that CO provides to regions reflects both the needs and special priorities of each program workload, as well as national and regionally-specific priorities. The RO must be aware of and apply these constraints and priorities when negotiating the CLIA budget with the States and

during the review and approval of subsequent quarterly expenditure reports. It is important that the required workload be accomplished within the approved budget. The RO, however, have some flexibility in determining each State's needs within its regional allocation. The RO should communicate significant problems or changes to the CO as soon as they are identified.

6420. THE SA AGENCY ANNUAL ACTIVITY PLAN

In accordance with established yearly schedules, the SA completes the Form HCFA-102, Budget Request form, (Exhibit 116), and forward it to the RO. Include a description of planned program activities for the ensuing fiscal year and a Form HCFA-105, Planned Workload Report, (Exhibit 119). Working with SA and HCFA CO, the RO assesses the amount of activity planned and the proposed cost to conduct the work by each State and helps to keep the costs in line for the nation as a whole. From this information and in discussions with the State and CO, the RO will be able to determine the adequacy and appropriateness of the programs planned by each State as they relate to the legislatively mandated goals and budget estimates. The information on the activity plan should agree with the State budget request.

6422. PLANNING THE ANNUAL WORKLOAD - SA PROCEDURES

The need for professional skills and additional personnel can only be ascertained after the workload is identified and a plan for accomplishing the work is outlined. Since the survey and certification program requires that laboratories be inspected within a biennial time-frame, the SA sets goals by categories of laboratory. The SA establishes schedules for surveys of the laboratories. The activity plan is to establish a program which permits survey and certification work to be done on an orderly basis throughout the year and with an even workload distribution over the one and two year cycle.

6424. ELEMENTS IN THE ANNUAL ACTIVITY PLAN--PLANNED WORKLOAD REPORT - SA PROCEDURES

For CLIA survey purposes, there are three types of certificates provided to laboratories. These include Certificates, Certificates of Waiver, and Certificates of Accreditation. For those holding a Certificate of Waiver, a survey may be conducted to investigate complaints. Also, a random sample of laboratories with a certificate of waiver is selected by HCFA for validation surveys. Those holding a Certificate are inspected once every two years and are evaluated in accordance with Federal regulations. Complaint inspections may also be performed. Those holding a Certificate of Accreditation are randomly inspected at an administrative goal of five percent. The specific validation surveys are assigned by the RO. If complaints are received about any laboratory, a survey can be scheduled to investigate the complaint.

The workload to be reflected in the State CLIA workload plan is to include initial surveys, re-visits or contacts, follow-up visits, and complaint visits for the various schedules of laboratories. The narrative plan is to conform to and confirm the numerical counts planned. The Form HCFA-105, Planned Workload Report, (Exhibit 119), is to be used in developing CLIA SA workload plans.

The Planned Workload Report lays out the SA Plan to conduct the surveys and other related activities for the fiscal year by laboratory schedule as it relates to workload volume and specialties. The SA identifies the estimated workloads and then, translate them into narrative staffing and activity plans, and project related costs.

6426. FORMAT FOR THE ANNUAL ACTIVITY PLAN - SA PROCEDURES

The SA uses any format for presentation of the SA annual activity plan. The SA includes the topics essential to the RO's management and budget review which are:

A. A narrative explanation (as necessary) for significant figures included on the workload data sheet.

B. A plan for using professional staff in survey and certification activities when more than one surveyor is required:

- o Division of responsibilities for survey;
- o Deployment of teams in relation to specific areas of workload; and
- o Geographic deployment.

C. A plan for meetings with appropriate special interest groups, e.g., informational and educational programs for Ombudsmen, consumer groups, State and county laboratory and medical societies, to discuss issues and concerns regarding CLIA implementation.

D. A list of CLIA activities delegated to personnel organizationally located outside the SA.

E. The names and health professions or specialties of currently qualified surveyors.

F. A description of the State's use of any laboratory testing or evaluation program in connection with CLIA activities.

G. An outline of program training planned for your staff:

- o Staff training meetings;
- o Formal courses attended;
- o Seminars;
- o In-service training programs; and
- o Special problems of decentralized agencies.

6428. SURVEY TEAM COMPOSITION AND WORKLOAD REPORT-HCFA-670 (EXHIBIT 74)- SA PROCEDURES

The Form HCFA-670 is intended to provide HCFA with the work-power utilization information needed to determine the total number of hours spent on each type of CLIA laboratory survey-related activity. From this and combined with other CLIA cost information, HCFA can compute the costs of performing the CLIA-related work and can compute the amount of money to be paid to a given SA to pay for the work performed. Laboratory surveyors, other State employees or contractors and others, including RO employees, involved in the CLIA-related processes must keep an accurate record of the number of hours spent working on a given laboratory's survey or similar CLIA activities. All payment to the State for survey work-power costs will be matched against the HCFA-670 data. Once the Form HCFA-670 data has been received, HCFA computes the cost of survey-related activities and initiates any necessary action to create a bill for costs not already paid for by the laboratory.

REMINDER: Hours spent performing State required activities that are in excess of those activities mandated by CLIA are not billed to CLIA. The SA does not complete a Form HCFA-670 for those hours.

The SA prepares the Form HCFA-670 for every type of CLIA survey-related activity including:

- o Initial surveys;
- o Recertification surveys;
- o Recontacts;
- o Complaint surveys;
- o Re-visits;
- o Validation surveys;
- o Sanction activities; and
- o Hearings/appeals.

For the most part, the SA completes a Form HCFA-670 after concluding all survey-related activities, including follow-up contacts and resolution of corrective action. The SA includes time spent on each activity and based upon employee records, beginning with the pre-survey preparation time and ending with the closeout of the survey activities, on the Form HCFA-670. (See Exhibit 74.)

Time spent by the RO staff conducting the oversight sample reviews of accredited and CLIA-exempt laboratories will be billed based upon the charges set forth in 42 CFR 493.645ff. The mechanism for reporting those hours is to be determined.

6430. BASIS FOR DETERMINING CLIA-RELATED COSTS - SA PROCEDURES

Public Law 100-578, CLIA 88, mandates that the CLIA program be completely funded by the laboratories being regulated. The total cost of the work expended by all CLIA personnel, both Federal and State, is to be paid by the regulated laboratories. More specifically, each laboratory is to pay all costs incurred in regulating that laboratory, including the costs of survey, complaint investigation, hearings and appeals (if the SA and HCFA are sustained) or other related CLIA outlays such as administrative and enforcement overhead.

There are circumstances in which the specific laboratory may not be specifically billed for the cost of the CLIA work-power expenditure, e.g., if a laboratory appeals an action and the ALJ sustains the laboratory or a settlement in favor of the laboratory is reached prior to the official hearing, the appeal-related work-power outlay (Federal and State) are entered on a HCFA-670, but the laboratory is not billed directly for these expenses. The SA prepares a Form HCFA-670 for the nonappeal-related work-power outlays and a separate Form HCFA-670 is prepared for those work hours spent in preparation for the appeal, hearing and related expenses. In either case, the SA and HCFA are paid for all CLIA work-power expenditures. The laboratory is billed for the survey-related costs that preceded the decision leading to the appeal, but not for the appeal costs.

If the SA and HCFA are sustained in the ALJ hearing or the laboratory agrees to the findings or settles prior to the hearing in a SA/HCFA favorable decision, the SA documents on the Form HCFA-670 all costs related to the action, e.g., hearing preparation, documentation, staff preparation time including the time spent preparing the Form HCFA-670. The laboratory is billed for those costs and the State is paid from the funds received. Unsubstantiated complaint costs are not be billed to the

laboratory by HCFA, but rather are paid from the administrative funds of CLIA. In such cases, the Form HCFA-670 that the SA submit initiates payment. No bill goes to the laboratory.

As the SA schedules each laboratory survey, it maintains a record of the time spent in preparing for and conducting and closing out the survey, including the monitoring and recontacts involved in resolution and the preparation for an administrative hearing of a laboratory appeal. As each CLIA survey or support activity is performed, the SA records the time spent on the activity. Thus, any time spent preparing for a laboratory survey and time spent in follow-up contacts to ensure compliance are shown for all CLIA SA or RO personnel involved. Telephone discussions, report preparation, on-site visits and even the time spent preparing the Form HCFA-670, are chargeable work-power expenditures. The SA reports the total time consumed for each laboratory action in hours at the close of the action in a Form HCFA-670, identifying the type of action that precipitated the work-power expenditure. HCFA records and stores the data when received. HCFA then multiplies the total hours reported by the dollar hourly rate computed for each State CLIA budget for that fiscal year. The computed dollar figure becomes the amount of the bill that is submitted to the laboratory involved in the specific CLIA action and which the SA claims payment.

Use the Form HCFA-670 (Exhibit 74) for reporting CLIA work-power expenses by both State and Federal oversight personnel. It is the mechanism for generating a laboratory bill and a State claim for payment for work-power expended.

6432. PROMOTIONAL AND PUBLIC INFORMATIONAL ACTIVITIES - SA PROCEDURES

The §1864 agreement assigns significant responsibilities to the SA for conducting public information (PI) activities. Similar activities are carried out by HCFA. The SA answers queries about CLIA when at all possible. CLIA queries are referred to the RO only if the information being requested is not available at the SA level or if it is clearly one that must be responded to by appropriate HCFA authorities.

Certain other professional relations activities fall into the dual categories of public information and public relations. SA personnel are to develop and maintain ongoing relationships with members of the health professions and their organizations. The SA should encourage employees to participate as speakers, panelists, or consultants at meetings of professional organizations (laboratory or medical technologist associations, hospital associations, medical societies) in the interest of furthering compliance with CLIA standards and objectives. These costs may be reasonable costs subject to CLIA funding.

6434. THE STATE BUDGET REQUEST

In the CLIA budget process, HCFA's CO and RO staffs obtain input from the States and laboratories to develop the baseline data needed to formulate each State budget. This data is used to develop the CLIA user fee revenues, workload estimates, expenditure, time parameters, and hourly rates. This is a negotiated process which starts with HCFA's preparation of the Budget Call Letter. Input for the Budget Call Letter includes an estimate of the revenues received from the laboratories, an estimated unit cost of each workload, time parameters, and a derived hourly dollar rate for the staff conducting agreed-to work.

The RO forwards the Budget Call Letter to the States which develop workload estimate and corresponding budget revenues by completing the Form HCFA-102, Budget Request (Exhibit 116) and the Form HCFA-105, Planned Workload Report (Exhibit 119). The completed Form HCFA-102 and Form HCFA-105, and the narrative supporting documentation are forwarded to the RO which analyzes the data presented and works with the SA to assure that the workload estimates are accurate

and reasonable for each these workload: Initial Surveys; Re-surveys, Follow-up Visit/Surveys, Complaint Surveys/Visits estimates. Once agreement on the workload estimates is achieved the number of Full Time Equivalent (FTE) employees is computed. Though the SA does not perform the oversight surveys for State-exempt laboratories, it is possible that SA may incur some related costs. If such costs do arise, it is important that they be identified to the RO so the RO can determine their appropriateness and advise the SA accordingly.

As the SA conducts CLIA work, the surveys are completed. The SA prepares the Form HCFA-670, Survey Team Composition and Workload Report (Exhibit 74), to begin the laboratory billing and State payment processes. Each quarter the SA completes the HCFA-102 detailing expenditures for the elapsed quarter and for the budget year to date. Analysis of this data will provide a complete status of revenues expended that can be compared to the total State approved budget. The SA should identify shortfalls and, if necessary prepare a Form HCFA-102, Supplemental Budget Request and submit it for processing and approval.

Funds provided agencies as a result of the budget request are used only for necessary expenses and only for CLIA-related expenses. The SA may shift funds from one expenditure category to another, except equipment or laboratory surveyor training funds which may only be reprogrammed with prior approval.

6436. STATE BUDGET REQUEST, CLINICAL LABORATORY IMPROVEMENT AMENDMENTS PROGRAM, FORM HCFA-102 (Exhibit 116)

The budget request is a detailed estimate of CLIA survey program costs. The SA classifies such costs according to the category of the proposed expenditure. Explanations for the specific categories of expense are essential in both budget preparation and subsequent analysis. Therefore, the SA should make sure the budget request contains complete rationale regarding each line item. The detail in which these statements are developed makes possible a close estimate of financial needs and enables the RO to make more rational adjustments in the total operating budget. Line item justification consists of narrative statements providing specific rationale for budgetary needs.

The basis for estimating line item expenditures will be the number of laboratories the SA intend to survey in one year and the number of work hours needed. The SA includes in the estimates the number of surveys to be initiated due to complaints; for enforcement purposes, such as to verify the correction of action items identified during a prior survey; and follow-up contacts or discussions required to close out a survey-related workload item.

- o RO Assistance.--RO personnel are available to assist in preparing budget requests. The SA should consult with appropriate RO staff on any problem with the budget preparation process. Begin consultations as early as possible and submit the budget in accordance with the due date provided by the RO. Timely submissions help assure timely HCFA completion of the budget approval process.

- o State.--Insert the name of your State.

- o Fiscal Year.--The fiscal year for which the budget request is being made.

- o Request.--Indicate if the submission is a regular, i.e., whole year budget submission, or a supplemental budget request for additional funds for the remainder of the fiscal year.

SECTION A - EMPLOYEE SALARIES AND WAGES REQUESTED.--The budget justification is to describe the type of staff being employed in the conduct of the CLIA workload, broken into the two categories, Professional and Clerical. The SA reports staffing estimates in two ways: The number of actual employees and the number of staff years in full-time equivalents. This will provide

the required number of surveyors and support personnel involved in the CLIA workload versus the actual work years of personnel involved in the CLIA workload. Place the number of employees in column (a), EMPLOYEES, and the computed number of Full Time Equivalents (FTE) work-power, in column (b), NUMBER OF STAFF-YEARS. The SA multiplies the estimated yearly salaries times the estimated work years and insert those dollar amounts in column (c) FUNDS REQUESTED.

SECTION B - OTHER FUNDS REQUESTED.--THE SA

1. Retirement Contributions and Fringe Benefits.--Enters the computed dollar value of retirement contributions and fringe benefits mandated by State/Federal law, Union/Management or Employee/Management agreements or other legally binding contracts/agreements. Explains the computation in the budget request narrative.

2. Travel.--Enters the estimated travel costs for CLIA personnel, including where appropriate, the per diem or the subsistence in lieu of per diem, applicable to the CLIA survey program. Derives estimated costs based on provisions of State law, regulation and administrative procedures applicable to travel of State employees. Indicate in the narrative budget justification an estimate of the expected number, type and extent of trips. For out-of-State travel, indicate the number of trips, purpose and basis for charges to the CLIA program. Include the basis for charges for all out-of-State travel other than to meetings arranged by HCFA.

3. Communications.--Enters the estimated costs to be incurred for telephone services, including costs for teleconferences, mail (including express mail), special handling, postage and postage stamps, postage meters, insurance on mailed items, postage due-charges, FAX costs and other communication-related expenses. The narrative budget justification should also address any unusual requests, such as for mobile phones, modems and similar items.

4. Office Supplies.--Enters the estimated cost of office supplies to be used by CLIA personnel only. Include the costs of paper, pencils, pens, envelopes, clips, pencil sharpeners and other usual desk materials, file baskets, books and other required desk reference materials, photocopier supplies, FAX supplies, computer equipment-related supplies, typewriter supplies, and other reasonable CLIA-related supplies.

5. Office Space.--(See §§6524-6534.) Enters the costs of office space, considering possible variations, and describe as follows:

o Agency in Identifiable Space.--Enters the costs of space that can be attributed to CLIA personnel use only. Analysis of the budget request and estimates must contain the following elements for each location:

- Total rental cost/pro-rata cost of CLIA space;

- Square feet of space/CLIA-related square footage;

- Cost per square foot; and

- Services included in the rental.

The SA identifies, also, office space that is State-owned and include it either separately or as part of the State's indirect cost rate.

o Office Space--Agency in Shared Space.--Analysis of base period expenditures and the budget estimate must contain these elements:

- Total cost of space to the agency;

- Basis of proration;

- Locations where CLIA staff are housed; and

- Estimate of square feet allocated to all State programs and those used by CLIA personnel.

State-owned space should be identified as such.

o Office Maintenance.--Includes in the budget estimate narrative, a breakout of the major items of expense, e.g., light, heat, janitorial service, machine repair. If office maintenance, in whole or in part, is included in the rental contract, the SA notes this fact. The SA need not separate the amount.

6. Equipment.--Enters the reasonable costs of equipment to support CLIA-specific positions such as desks, chairs, typewriters, computers and computer-related equipment, file cabinets, tables, and other machines (FAX machines, photocopiers, etc.) necessary for CLIA operational, administrative or management needs. Equipment authorized in the present fiscal year, which will not be purchased by the end of the fiscal year, must be requested in the budget for the succeeding fiscal year if the SA still needs it. In addition to line item justification, the SA documents the budget estimate through the use of the Form HCFA-1466, State Agency Schedule for Equipment Purchases. (See Exhibit 54.)

7. Training.--The budget estimate should provide for the cost of training CLIA personnel. The SA uses the number of employees to be trained rather than FTE's when computing this figure and includes the cost of the courses to be taken, the cost of travel and per diem associated with training sessions. The narrative justification should indicate the types of courses to be taken by employee type and by number of employees to be trained.

8. Consultants.--Provides the estimated cost of consultants or those who are not State employees but who are used on a part-time, temporary, or fee-for-service basis to perform CLIA-related work.

9. Subcontracts.--Provides the estimated cost of subcontracts to be employed in the conduct of CLIA-related work. Subcontract costs attributable to CLIA survey activities are allowable and payable. The budget justification should provide in detail, the reasons for, and approximate cost of each separate subcontract.

10. Miscellaneous.--Provides the estimated cost of other items that have not been reported in any of the preceding classifications, breaking them into compatible groups of expenses (sections a, b, c, and d), if possible. The SA uses narrative justification to explain all proposed expenditures.

SECTION B - TOTAL.-- Enters the total of lines 1-10.

SECTION C - INDIRECT COSTS (Approved Rate x Base).--Provides the rate negotiated and approved by the HHS Division of Cost Allocation for use during the fiscal year, together with the line item base it is applied against. Expenditures included in this category must not be duplicated under direct costs.

SECTION D - TOTAL BUDGET REQUESTED.--Enters the estimated sum total of Sections A, B and C.

SECTION E - HOURLY RATE REQUESTED.--Divides the Total Budget Requested by the Total Number of Staff Years and divide again by the Hours Available per Staff Year to derive Hourly Rate, as in the example.

Example: Budget Amount.....$100,000
Divided by Staff Years...___2
Equals.....$ 50,000 per Staff Year

$50,000 divided by 1,600 hours in the Staff Year Formula equals a $31.25 hourly rate.

6438. HCFA-105, PLANNED WORKLOAD REPORT - CLIA (Exhibit 119) - SA PROCEDURES

The SA uses the Form HCFA-105 only to estimate the laboratory survey workload under CLIA. The SA provides an estimate of the planned workload for each laboratory schedule. The laboratory schedule can be found in the CLIA user fee regulation.

A completed HCFA-105, Planned Workload Report, should accompany a HCFA-102, Budget Request, and an analytical budget justification narrative anytime a CLIA budget request or supplemental budget request is submitted to the RO. It is essential that the estimates of planned workloads be as accurate as possible. Accurate workload estimates can be developed from prior workload history, where one exists, and results in a more accurate and timely budget approval.

The SA:

Heading.--Inserts State name and Federal fiscal year in the appropriate boxes.

Column (a), Number of Sites.--In reviewing the workload plans for the year, determines the number of separate laboratory sites that will be visited for surveys, follow-up visits and complaints.

Column (b), Initial Visits.--Enters the planned number of initial compliance determination surveys (laboratory surveys) to be conducted for each type of laboratory. (See 42 CFR Part 493.638ff for the schedule of laboratories and fees to be charged.) Includes a five percent sample of those that hold a Certificate of Accreditation since a sample of those laboratories are to be inspected for compliance in accordance with the SA oversight role and responsibility.

Column (c), Resurvey Visits.--Enters the total number of non-initial compliance surveys planned. This figure is to reflect the number of other than first time laboratory surveys to be conducted in a fiscal year.

Column (d), Follow-up Visits.--Enters the number of follow-up surveys planned for the fiscal year. These are visits to verify compliance or to verify a completed plan of corrective action or for some other enforcement purpose. Prior history may indicate that a portion of all laboratories require actual follow-up visits as opposed to re-contact via telephone or mail to finalize the laboratory compliance survey report. Follow-up visits are not routinely required by CLIA.

Column (e), Complaint Visits.--Enters the number of complaint surveys planned for the fiscal year.

Column (f), Total Visits.--Provides the totals to column (f) and computes the totals at the bottom of the form. Signs and dates the form and submits it with the Form HCFA-102.

6440. FORM HCFA-1466, STATE AGENCY SCHEDULE FOR EQUIPMENT PURCHASES (Exhibit 54) - SA PROCEDURES

Usage.--This form has a two-fold purpose: The SA uses it when requesting budget approval of equipment purchases, and completes and submits it to the RO when an actual purchase has been completed. The form is applicable for CLIA, LTC and non-LTC equipment requests and purchases. A separate form must be prepared for equipment purchase for each program. When equipment is actually purchased, the SA prepares and forwards a Form HCFA-1466 with the appropriate program's budget expenditure report.

The SA:

Heading.--Inserts the official name of the agency and the State name in the designated spaces. Indicates the period for which equipment funds are requested. Indicates if this is accompanying a regular budget submission or a supplemental budget submission.

Column (a), Description of Equipment.--Enters the items of equipment being requested or reported as purchased. Uses an asterisk or other notation to note items previously approved by the RO but which are being re-budgeted or requested again. On the bottom or reverse of the form explains why the purchase was not completed in the prior budget period.

Column (b), Number of Items on Hand.--Lists the number of similar items on hand in the State CLIA survey unit at the time the form is prepared. If a new and different item is being shown, shows "None" in this column.

Columns (c) and (d), Number of Units (Additional-c) or (Replacement-d).--Lists the number of units being requested in the appropriate column, (c) or (d).

Column (e), Unit Cost.--Enters the unit cost of each item in column (a).

Column (f), Gross Cost.--Computes and enters the gross cost for each item in column (a) by multiplying the number of units in columns (c) or (d) by the unit cost, column (e).

Column (g), Net Cost.--Enters the amount shown in column (f) for each item listed in column (a), less any amount shown in column (g).

Total Net Cost of Equipment.--Enters the sum of all amounts shown in column (g) above. For CLIA, enters this amount on the Form HCFA-102, item 6.

Date, Signature, Title.--Dates and signs the Form HCFA-1466. Shows the title of the individual signing the schedule.

6442. FORM HCFA-1465A, STATE AGENCY BUDGET LIST OF POSITIONS, (EXHIBIT 47)

Usage.--The SA uses the Form HCFA-1465A for all program position approvals. Separate forms and approvals are required for each of the programs: Title XVIII NON-LTC, Title XVIII LTC, Title XIX and CLIA. The SA uses the most recently approved form or computer form format to assure proper information collection.

The SA:

Heading Information: Name of Agency.--Inserts official name of the agency.

State.--Enters name of State.

Fiscal Year.--Enters the Federal period for which funds are being requested.

Position Title/Name.--Lists each position type employed and the names of each employee actually occupying each position type. This will help the SA distinguish between the number of positions it has filled as opposed to the number allocated. Differences could mean substantially different approved budget levels. This information may prove useful when determining the number of employees that require training in a given discipline. Remember that individual employees are trained, not the number of full-time equivalents employees.

City Where Located.--Provides this for all position types and employees. Monitors differences and changes in staffing levels by location.

No. of Pos. (Number of Positions).--After completing the Position Title/Name columnar entries for all positions, enters the number of actual allocations for each position, e.g., the actual number of employees occupying that position title.

Staff years.--Computes the actual number of staff-years by Position Title. Representations of full and part-time employees are no longer necessary. Rather, it is important to compute the number of work or staff years using the work hours employed by each Position Title. Includes anticipated overtime usage by all categories of positions in this computation.

Funds Required.--For each Position Title, computes the budget dollars required by multiplying the total work years for each Position Title times (X) the total dollar figure computed for and relevant to that Position Title. Includes overtime in the calculations for all the positions listed.

If possible, the SA discerns from the Position Titles which are professional and which are clerical positions. If the SA cannot, do whatever is necessary to clarify and classify all positions accordingly. Once the SA has classified the positions into the two types, total the staff years and dollar amount for each of the two categories.

6444. STATE BUDGET REQUEST SUBMITTAL--CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

A. List of Materials and Order of Assembly.--The SA assembles the budget documents in descending order, as follows:

- Budget Request CLIA-HCFA-102, (Exhibit 116);
- Form HCFA-105 Planned Workload Report, (Exhibit 119);
- Form HCFA-1465A, SA Budget List of Positions, (Exhibit 47);
- Form HCFA-l466, SA Schedule for Equipment Purchases, (Exhibit 54);
- State justification arranged in line item order; and
- Any exhibit referred to in the line item justification.

B. Routing and Number of Copies.--The SA forwards the original and one copy of each document to the RO. It may be possible to forward or transmit much of the data in a computer file format that is easier to handle and manipulate. RO and SA agreements to facilitate such improvements are encouraged. The SA submits the budget in accordance with the due date provided by the RO but no later than July 30 preceding the Federal fiscal year to be funded. The deadline ensures that HCFA can complete the budget approval process in time to prevent an interruption in cash flow when one fiscal year ends and the succeeding year begins.

6446. DEVELOPING BUDGET APPROVAL - RO PROCEDURES

A. Budget Request Package.--In response to the budget call letter, the RO receive a CLIA budget submittal from each SA. It is preferable that all data be provided in two forms, automated when available and in signed hard copy. All State or regionally prepared budget forms and spreadsheets must be identical to the nationally approved HCFA form or spreadsheet. Where computerized forms are used, the data may be transmitted electronically, e.g., from State to RO, RO to CO. Disks containing the information may be mailed between offices as long as a proper mailer is used, i.e., one that protects the disk and data. The automated copy of the data should be followed by signed hard copies of each budget form. Each budget package should contain:

- Form HCFA-102, State Agency Budget Request;
- Form HCFA-105, Planned Workload Report;
- Form HCFA-1466, State Agency Schedule For Equipment Purchases;
- Form HCFA-1465A, State Agency Budget List of Positions; and
- The narrative budget plan that explains hiring, training plans, equipment purchases, budget exceptions, and variances or omissions in general. Documentation should be sufficient to support the budget plan.

B. Basis for Budget Approval.--The basis for approving the line item budget is the number of facilities to be surveyed and the amount of staff and money needed to survey them. The 1988 amendments to CLIA mandate that all laboratories be surveyed every two years. Thus, the budget plan should address itself to the basic question of how the SA will accomplish this goal. It is important that the RO evaluate the accomplishments of the past performance period to determine the goals that need to be set and accomplished for the next performance period. Budget constraints or unexpected revisions may effect hiring or any of the myriad of budget line items. Revised national and regional priorities may also impact upon workload plans and accomplishments, so the RO should be flexible and diplomatic in subsequent negotiations with the SA. The RO should not rely solely on written justification when approving a State's CLIA budget.

C. Line Item Negotiation and Approval.--The budget approval is a detailed concurrence or revision to State estimated survey program costs. The RO negotiates the budgets by line item, according to the category of the proposed expenditure. The approval process is between the RO and the SA. The RO should be able to explain any adjustments and the method used to compute each amount.

The RO should caution the State that funds provided agencies, as a result of the budget approval, must be used only for necessary expenses and that financial shortfalls may occur that would dictate reduction of budget allocations to each State after approval. This will reduce the potential for adverse consequences should there be a need to reduce expenditures.

D. Payable Reasonable Costs.--The SA is entitled to receive advances to and payment of all reasonable costs for performing the CLIA survey workload. CLIA funds cannot be used to pay the SA for any non-CLIA related expenses incurred. Though CLIA-dedicated support staff will better facilitate the computation of CLIA-related expenses for budgeting purposes, it is possible that shared staff, who are involved in supporting multiple programs, may be employed. Since CLIA will pay States only for CLIA-related expenses, proper proration of expenses is mandatory.

Reasonable costs include all necessary expenses in accordance with the standards and are described in the manual. Any class or kind of administrative expenditure that is properly chargeable to Federal

CLIA funds under approved plans may be funded by CLIA revenues. SAs are expected to exercise due care in the expenditure of funds, understanding that the funds must be used only for CLIA-approved activities and procurement.

E. Projected Workload.--The projected workload, program emphases, the SA's hiring and training plans, and the experience of the 12-month preceding period, if appropriate, are the primary factors for the RO to consider when approving the line item budget. The RO uses these factors as a guide, negotiate the budget in a fashion that assures that national and regional goals are met. When the RO makes changes to the State's proposal, it provides the rationale for the proposed change. The RO rationale should include:

- o The revised estimate;
- o The rationale for the change; and
- o The basis for computing the revised estimate.

F. CO Assistance.--CO personnel are available to assist with negotiating budget approvals. The RO may consult with CO staff on any issues that are troublesome. The RO should raise concerns or issues as early as possible in the budget process. Prompt consultation can minimize the impact of many problems.

How the SA establishes and maintains controls is less important than the fact that a control system is in place for the CLIA workload. A by-product of the control system should be management information that is useful in managing the pending workload. Thus, some ability to capture data about workloads scheduled, pending and completed by laboratory schedule and employee type (to the extent possible) should exist in whatever system or mechanism the SA chooses to use. Whatever form the controls take, it is important that documentation of actions involving the laboratories be retained in a retrievable format that allows for review of the data, if necessary. Individual laboratory case records should be permanent case records that are accessible for review and analysis at a later date. It is also essential that the RO maintain the laboratory action control records so that they can be readily accessed should the need arise. The RO uses established controls for following up on pending CLIA actions, scheduling surveys or complaint visits, PoC follow-up visits, and other CLIA-related activities.

6448. RO STATE AGENCY BUDGET REVIEW - FORM HCFA-102

A review of the line items in the Form HCFA-102 (Exhibit 116) should reveal that they conform to the guidelines that follow. It is important that the RO obtain an explanation of all line items that contain no money amounts. Blanks or zeros in items such as office space, communications, and supplies or equipment should be explained in writing. If the cost for one or more line items is included in the indirect cost allocation rate reported on the form, it should be so stated and explained.

6450. EMPLOYEE SALARIES AND WAGES - RO PROCEDURES

A. Distribution of Staff Time for Program Purposes.--CLIA funds may be used to pay CLIA-only program expenditures. However, some personnel may be involved in multiple program activities. The RO should determine that a method for capturing the appropriate manpower split by program is developed when such time sharing occurs. The proper pro rata splits must be employed and documented to facilitate proper budget preparation, approval, and execution. Distribution of shared staff time to the appropriate separate program areas of State activity is required.

In the event staff are shared, the RO requests that periodic studies be conducted that will determine the proper prorate formula. A prorated portion of the cost of such studies, work sampling, data recording, and reporting is also a necessary and reasonable CLIA-related expense.

B. Determination of Necessary Staff.--The following method may be used by the SA to determine a proper split of costs for CLIA versus other State program administration costs:

- o Determine the number of inspections and related manpower needed to fulfill the requirements of the CLIA laboratory inspection program; and

- o Determine manpower requirements which are related to the requirements of other programs.

The ratio of countable CLIA activities to the sum total of the countable activities of all programs can be applied to the cost of the total multi-program activity.

Using this prorate method is acceptable when miscellaneous costs cannot be specifically identified as a CLIA or other program-specific expense. However, specific applications of this general principle will have to be developed jointly by the SA and the RO. This method permits adjustments for circumstances a particular agency may encounter. However, it is possible that such difficulty to identify charges may already be accounted for in the indirect cost allocation rate and should not be included here. If the RO is in doubt as to whether all or part of a line item is already included in the indirect cost allocation rate, contact CO. They will contact the Office of Assistant Secretary for Management and Budget, HHS, to determine if such is the case. There are instances in which commonly-shared personnel, such as a typing pool, may be covered by agreement with the Department in the indirect cost allocation. If it is included in the Indirect Cost Allocation, inclusion in another line item would create double billing for this item. Since no two indirect cost allocation agreements are exactly the same, the RO should not presume that what goes for one SA goes for the others in its region.

All such SA proposals to use sampling or prorate formulas must be approved by the RO before charges can be made under them. The RO may conduct studies, or direct that they be conducted by the SA to verify the results.

6452. RETIREMENT CONTRIBUTIONS AND FRINGE BENEFITS - RO PROCEDURES

Retirement and fringe benefits that are in accordance with State and Federal laws are acceptable as CLIA reimbursable expenses. It is possible that these charges may already be accounted for in the indirect cost allocation rate and should not be included here. If in doubt, the RO should contact CO. CO will contact the Office of Assistant Secretary for Management and Budget, HHS to determine if these costs should be included here.

6454. TRAVEL - RO PROCEDURES

The cost of travel, including, where appropriate, per diem or subsistence, in lieu of per diem, may be charged to CLIA. The travel must be done in accordance with the State's laws, regulations, and administrative procedures applicable to travel by State employees.

A. CLIA Laboratory Survey and Administrative Travel.--Laboratory survey travel includes travel to and from a facility:

- o To conduct laboratory inspections;

- o For revisits or to verify PoCs;

- o To perform laboratory complaint or oversight inspections; and

- o For meetings with HCFA personnel on CLIA-related activities.

Administrative travel is defined as travel for management purposes related to the CLIA laboratory inspection program:

- o To attend agency administrative staff meetings related to CLIA;
- o To attend State CLIA program meetings or activities conducted or sponsored by HCFA; and
- o For planning or liaison visits to other agencies concerning certification.

Travel to participate in sanction meetings or negotiations or to appear before an ALJ in a hearing (to provide testimony or support for a sanction activity against an alleged non-compliant laboratory) may also be charged to CLIA.

B. Travel Involving Multiple Program Activities.--Travel expenses for an employee performing multiple program activities (Medicare/Medicaid and CLIA) for the State should be prorated in accordance with the distribution of direct personal service time spent on each program involved in and recorded for each trip. Alternatively, such trip records may be accumulated for an accounting period and prorated accordingly. For example, if at the end of the period such records showed that two-thirds of the employee's productive time while in travel status was devoted to the State survey and certification program, and one-third of the time was devoted to CLIA activities, then the agency would charge one-third of the total travel cost to CLIA (including transportation, per diem, etc.) and the other two-thirds to the other appropriate program funds.

C. Training and Conference Travel.--This category of travel includes that travel which is not directly related to the line operations of surveying laboratories, consultation, and administration, as described above. Examples of travel performed are:

- o Incident to orientation and basic training of new employees; and
- o For meeting the needs of experienced employees for retraining.

Also included is travel relating to:

- o Conferences;
- o Meetings;
- o Training;
- o Workshops; and
- o Seminars if the agenda material is directly related to the laboratory survey functions of the agency.

Travel for such purposes may be funded by CLIA.

It is possible that some common travel charges may already be included for payment by the indirect cost allocation and should not be included here. If in doubt as to whether all or part of a line item is already included in the indirect allocation rate, the RO should contact CO. They will contact the Office of Assistant Secretary for Management and Budget, HHS, to determine if such is the case.

6456. COMMUNICATIONS AND SUPPLIES - RO PROCEDURES

A. Basis for Charges.--Communications and supplies should be direct CLIA charges if separable from other program costs and identifiable as to unit cost. These expenses may be charged on a prorata basis if used for multiple program purposes. For example, if long distance calls are routed through a switchboard or can otherwise be identified as to program, the CLIA calls can be made a direct charge. Otherwise, all long distance charges should be prorated, using an identifiable and justifiable method or formula. It is neither equitable nor legal to charge the CLIA program for installation and rental of telephones used exclusively by other programmatic State staff. If lines and telephones are shared by CLIA and non-CLIA personnel, payment must be on a prorata basis. The SA method of proration or the formula used must be included in their budget supporting documentation. Any blank or zero in this item must be explained. If it is included in the indirect cost allocation rate, it should be so stated.

B. Communications.--Such items as services including teleconferences, telegraph messages (except such items as are payable on travel expense accounts), postage, postage meter charges, printed stamped envelopes, registry and special delivery or express mail fees, insurance charges on fourth class mail, or postage due charges for CLIA employees and CLIA-program related activities are chargeable to CLIA.

For services such as satellite training or conferences, the SA has been advised to contact the RO to determine if the expense is a reasonable expense. The RO weighs the facts on an individual basis when such an inquiry is received. If found to be reasonable and necessary, it may be incorporated in the CLIA-approved budget. Expenses that, in some instances, may be justifiable as reasonable are those for:

- Mobile phones,
- Modems, and
- FAX machines and other communication related expenses.

If the RO concurs that the circumstances do indeed substantiate such an expense, the RO may include it in the approved budget computations. It is incumbent upon the SA to be in close consultation to assure that any planned unusual expenses are approved.

C. Supplies.--The items that follow are payable by CLIA if they are used to support CLIA personnel and CLIA-related activities:

- Such general office supplies as paper, pencils, folders, unstamped envelopes, clips, etc.;
- Non-consumable items such as staplers, pencil sharpeners, file baskets, books, etc., which do not exceed a $10 cost per unit;
- Printing or duplicating expenses and the cost of procuring forms such as printed or duplicated general office forms; and
- Costs of transportation or shipment of any of the above items.

The $10 cost-per-unit above shall apply unless a different amount is specified by State law, in which case the amount so specified shall control. If purchases are co-mingled with other than CLIA program purchases of the same nature, documentation and justification of the expenses, on a prorata basis is necessary.

It is possible that some common communication and supply charges are included for payment in the indirect cost allocation agreement negotiated by the State or SA with HHS. If so, they should not be included here. If in doubt as to whether all or part of a line item is already included in the indirect cost allocation rate, the RO should contact CO. They will contact the Office of Assistant Secretary for Management and Budget, HHS, to determine if such is the case.

6458. OFFICE SPACE - RO PROCEDURES

A. Cost of Office Space.--The cost of office space for CLIA laboratory survey functions is a proper charge against CLIA funds. The rules governing all such rentals and leases are the same for CLIA as they are for all other HCFA rentals and leases. These guidelines replicate those rules and guidelines. Such charges may take the form of:

o Rent, service, and maintenance cost in privately owned buildings;

o Monthly rental charges based on the cost of initial construction or purchase of publicly owned buildings; or

o Meeting the costs of service and maintenance in lieu of rent in publicly owned buildings.

In addition, charges may be made for repairs and alterations to either privately or publicly owned buildings. Payment usually should be made only for periods of occupancy. If unusual situations arise and no precedent exists, the RO consults with CO before the RO approves the State request.

B. Standard of Comparable Rental.--Charges against CLIA funds for office space must follow other HCFA guidelines and may not exceed the rental rate of comparable privately owned space in the same or similar locality. Because the rental rate of comparable privately owned space is not a fixed amount for any particular locality, the rental rates may vary within a locality as well as between localities. However, a realistic determination of the rental rate of comparable privately owned space must be made.

The basis and documentation for the establishment of the rental rate of comparable privately owned space should be kept on file in the SA. The RO may want to obtain a copy of the documentation in any precedent setting situation.

C. Privately Owned Space.--Charges against CLIA funds for privately owned space, including expenses of services and maintenance, repairs, and alterations, must not exceed the rental rate of equivalent space and facilities in the same or similar locality. (See §6826.)

D. Space in Publicly Owned Buildings.--The following standards apply to charges for office space in a publicly owned building:

o Actual Cost which is the amount charged for office space in a publicly owned building must not exceed actual costs over a long-run period. The SA is required to produce records of actual costs if the RO wishes to examine them; and

o 75% Rule which is the amount charged for office space in a publicly owned building may not exceed 75% of the lowest comparable rental for privately owned space unless there are special considerations justifying a greater charge. Use of this standard should be used only as an interim measure in the absence of actual cost data. This allows the SA to claim costs that are not in excess of 75% of the lowest cost of privately owned space. The SA is allowed to do this without prior review or approval by the RO.

When a monthly rental charge based on the cost of initial construction or purchase of publicly owned buildings exceeds 75% of lowest comparable rental for privately owned space or when the cost of service and maintenance in lieu of rent in publicly owned buildings exceeds 75%, the SA is required to obtain prior approval from your office. The RO may wish to consult with CO prior to granting approval for such expenditures.

It is possible that some common space charges are included for payment in the indirect cost allocation agreement negotiated by the State or SA with HHS. If so, they should not be included here. If in doubt as to whether all or part of a line item is already included in the indirect cost allocation rate, the RO should contact CO. CO will contact the Office of Assistant Secretary for Management and Budget, HHS, to determine if such is the case.

E. Charges Based on Meeting Cost of Service and Maintenance.--When the total charges for service and maintenance in a publicly owned building exceed 75% of the lowest comparable rental for privately owned space, the SA must submit, prior to its claim, the following data for review and approval by HCFA:

- Total useable floor space and the amount of space allocated to the CLIA laboratory inspection program personnel;
- Total costs of service and maintenance and the portion to be charged to CLIA funds;
- The elements of cost; and
- The rental cost of comparable privately owned space with at least three statements of appraisals.

6460. EQUIPMENT - RO PROCEDURES

Form HCFA-1466 should be attached to the budget package the RO is reviewing. Purchases planned should conform to the latest HCFA hardware and software acquisition guidelines. Documentation to support the proposed purchases should be complete. Reasonable purchases of equipment to support CLIA specific positions are permitted. Such purchases may include desks, chairs, typewriters, computers and computer-related equipment, file cabinets, tables, and other machines (FAX machines, photocopiers, etc.) necessary for CLIA operational, administrative, or management needs.

When the RO reviews the Form HCFA-1466, it checks to see that the SA has included appropriate details and reasonable requirements. If purchasing new computer systems, peripherals, such as printers, being planned should appear on this form. If printers are not shown, the RO should question what the SA will use to print products. Software being purchased in conjunction with the hardware purchase would not be included on this form, but rather would show up as a miscellaneous item on the Form HCFA-102. It is wise for the RO to review the software being considered. It should comply with HCFA guidelines and software standards. Consultation with both the SA and CO may be necessary and is advisable if plans for unusual purchases are noted.

Equipment authorized in the present fiscal year which will not be purchased by the end of the fiscal year must be requested in the budget for the succeeding fiscal year if still needed by the SA. If hiring constraints are going to restrict staffing plans, it is advisable that the RO and the SA reevaluate the timing of planned equipment purchases. Planning equipment purchases sufficient to provide for those to be hired should be considered.

6462. TRAINING - RO PROCEDURES

The budget request should provide for the cost of training CLIA personnel. The SA should use the number of employees to be trained, rather than full time equivalents (FTEs) when computing this figure. Included should be the cost of the courses to be taken, the cost of travel and per diem associated with training sessions. A narrative justification should indicate the types of courses to be taken by employee type and by number of employees to be trained.

It is possible that some training costs may have been included in the indirect cost allocation agreement negotiated by the State or SA with HHS. If so, they should not be included here. If in doubt as to whether all or part of a line item is already included in the indirect cost allocation rate, the RO contacts CO. CO will contact the Office of Assistant Secretary for Management and Budget, HHS, where copies of the agreements are maintained, to determine if such is the case.

6464. CONSULTANTS - RO PROCEDURES

The SA should include the proposed cost of hiring consultants who are not State employees but who are used on a part-time, fee-for-service, or temporary basis to perform CLIA-related work.

6466. SUBCONTRACTS - RO PROCEDURES

The SA should include projected cost of subcontracts to be employed in the conduct of CLIA-related work. Subcontract costs attributable to CLIA survey activities are allowable and payable. The SA budget justification should provide the RO with the specific details, the reasons for, and approximate cost of each separate subcontract.

6468. MISCELLANEOUS - RO PROCEDURES

Reported in these spaces should be any unusual budgeted items which have not been reported in any of the preceding classifications. To facilitate decision making, the SA should have attached to the budget package a narrative justification that explains all proposed expenditures. The RO should consult CO as necessary to resolve any questions.

6470. INDIRECT COSTS - RO PROCEDURES

The indirect costs provided would be the rate negotiated and approved by the HHS Division of Cost Allocation for use during the fiscal year, together with the line item base it is applied against (approved rate x base). The Department negotiates these rates with States, SAs, or programs. The rate negotiated may be for a whole State or for each program or grant in a State. It is probable that no two rate formulas include the same provisions. It is important that CLIA not pay the SA for anything that the SA is going to be paid for by any other program or provision. Where doubt exists, the RO questions any budget item and assure that an investigation is initiated. If the SA is unfamiliar with what is included in the indirect cost allocation and cannot get clarification for the RO from their financial experts, the RO contacts CO. Provide as much detail as the RO can as early in the budget process as possible so that the Office of the Assistant Secretary for Management and Budget can be queried for an answer.

6472. HOURLY RATE REQUESTED - RO PROCEDURES

The dollar amount of the hourly rate of payment requested by the State is usually computed by dividing the total budget cost by the agreed upon number of available hours for actual survey-related activities.

6474. PLANNED WORKLOAD REPORT - FORM HCFA-105 - RO PROCEDURES

Form HCFA-105 (See Exhibit 119) provides the State's estimate of the number of laboratory surveys it expects to perform in the budget period. The workload plan will list by laboratory type (schedule) the number of surveys to be conducted in the fiscal year. The workload report should reveal in detail how the SA plans to do the work. The State is required to survey every laboratory that does not have a certificate of waiver, a certificate for PPM procedures, or is under Federal jurisdiction every two years. It is essential that the estimates of planned workloads be as accurate as possible and be at the levels mandated by national and regional goals. The RO will be able to determine the propriety of the workload plans by review of prior workload history, where they exist, and evaluation against regional and national goals. The workload plan submitted should be supported by the other parts of the budget plan. If it does not provide sufficient detail from which the RO can determine that the work paid for will be accomplished, the RO must obtain the needed information or clarification. Negotiate discrepancies to acceptable levels.

6476. SCHEDULE FOR EQUIPMENT PURCHASES - FORM HCFA-1466 - RO PROCEDURES

A. Usage.--The HCFA-1466 (see Exhibit 54) serves two purposes: it is used when requesting initial budget approval of equipment purchases and is completed and submitted to the RO when an actual purchase has been completed. When equipment is actually purchased, the State should prepare and forward a revised Form HCFA-1466 with the quarterly expenditure report, Form HCFA-103.

B. Completion of the Form.--

Name of Agency.--The official name of the agency and the State should be in the appropriately designated spaces. The period for which equipment funds are requested should be completed. The SA should indicate if the submission is accompanying a regular or supplemental budget submission or an expenditure report.

Column (a), Description of Equipment.--Entered here are the items of equipment being requested or reported as purchased. Items previously approved but which are being rebudgeted should be included and noted by the SA. The State submission for approval will include supporting comments on the bottom or reverse of the form. It should also explain why a purchase was not completed in the prior budget period, if such is the case. If this justification is missing, the RO obtains the justification from the SA.

Column (b), No. of items on hand.--The number of similar items on hand (in the SA's inventory) at the time the form was prepared should be listed. SA equipment planning for one program should not be co-mingled with those of another. If sharing is taking place, the equipment costs should be prorated.

If this purchase represents a new and different item, "None" should be shown in this column.

Columns (c) and (d), Number of Units (Additional) or (Replacement).--The number of units approved by the SA should be listed. Are these to be replacement units or additional units? Is employee sharing of equipment done currently? Is equipment sharing a realistic and manageable option? Do not arbitrarily dismiss such options as viable alternatives to one-for-one equipment purchases.

Column (e), Unit Cost.--The unit cost for each item listed in column (a) should be entered here.

Column (f), Gross Cost.--The SA computes and enters the gross cost for each item in column (a) by multiplying the number of units in columns (c) and/or (d) by the unit cost, column (e). Column c + column d (x) column e = gross cost, column (f).

Column (g), Net Cost.--Shown here should be a summarized total amount for each item listed in column (a). This may be the same figure as that shown in column (f). If there are reductions that should be applied to the gross cost, thus increasing or lowering the net cost, the reduction should be explained and the proper Net Cost should be entered in column (g).

Total Net Cost of Equipment.--This is the sum of all amounts shown in column (g) above. This amount should have been entered by the SA on the HCFA-102, item 9. If the RO approves this amount, it enters the figure on the HCFA-104, item 6, column (c).

Date, Signature, Title.--The form must be dated and signed by the SA. The title of the individual signing the schedule should be shown.

6478. PREPARATION OF LIST OF POSITIONS - FORM HCFA-1465A - RO PROCEDURES

A. Usage.--Form HCFA-1465A (See Exhibit 47) is to be used for all program position approvals. Separate forms and approvals are required for each of the following programs:

- o Title XVIII NON-LTC;
- o Title XVIII LTC;
- o Title XIX; and
- o CLIA.

It is important that the most recently approved form be used by the SA to assure proper information collection.

B. Form Completion.--

Name of Agency.--The SA should insert the official name of the agency.

State.--The SA enters name of State.

Fiscal Year.--The SA enters the period for which funds are being requested.

Position Title/Name.--The State should list each position type employed and the names of each employee actually occupying each position type. This will help the RO distinguish between the number of positions the SA has filled as opposed to the number they have allocated. Differences could mean substantially different approved budget levels. This information may prove especially useful when determining the number of employees that require training in a given discipline. Remember to count the number of employees who require training, not the number of FTEs.

City Where Located.--This must be provided for all position types and employees. This will help the RO monitor differences and changes in staffing levels by location and may prove to be a source of information about the existence of multiple locations that may have larger program implications.

Number of Positions.--After completing the position title/name columnar entries for all positions, the SA should enter the number of actual number of employees occupying that position title.

Staff Years.--The State should have computed the actual number of FTEs by position title. Representations of full and part-time employees are no longer necessary. Rather, it is important to compute the number of work or staff years using the work hours employed by each position title. Overtime usage anticipated by all categories of positions should be included in this computation.

Funds Required.--For each position title, the SA computes the budget dollars required by multiplying the total FTEs for each position title times the total dollar figure computed for and relevant to that position title and includes overtime in the calculations for all the positions listed.

The RO should be able to discern from the position titles, which are professional and which are clerical positions. If the RO cannot, it should do whatever is necessary to clarify and classify all positions accordingly. Once the RO has classified the positions into the two types, the RO may wish to total the staff years and dollar amounts for each of the two categories. If needed, the RO may transfer the totals to the appropriate lines of the Form HCFA-102.

6480. LINE ITEM APPROVAL FOR PERSONAL SERVICES - RO PROCEDURES

In negotiating budgets, it is advisable to set a limit on the number of full-time equivalents chargeable to the CLIA program budget. With limits in place, a SA cannot exceed the approved full-time staff levels without prior consultation and authorization. This will enable the RO to monitor all discipline staffing, especially the actual number of on-board surveyors, and allow the RO to better analyze State requests and requirements for additional support staff.

6482. NEED FOR ADDITIONAL FUNDS - RO PROCEDURES

SAs should periodically check their current rate of expenditure. If it appears that expenditures may exceed the budget approved or the current allotment, the SAs should consult with the RO as soon as possible.

A. Adjustment in Quarterly Allotments.--During the first three quarters of the fiscal year (October - June), if the agency concludes that expenditures will exceed the current allotment, an information statement should be submitted to the RO. This statement should explain in which line items the SA believes additional funds will be needed and give the agency's reason for this conclusion. SAs may request an adjustment in the quarterly allotment schedule to make additional funds available at this time. A supplemental budget should be submitted when it appears funds will be exhausted before close of the fourth quarter of the fiscal year.

B. Supplemental Budgets.--At the beginning of July each year, SAs should review their fiscal requirements for the balance of the fiscal year. If at this time it appears that additional funds will be required, the SA should submit a supplemental budget. The supplemental budget should be completed for the full fiscal year and include a statement concerning the anticipated expenditures in each category and the net additional amount needed. The supplemental request should be prepared on the same form(s) and in the same number of copies as a regular budget request. Supporting information comparable to the kind found on regular requests should accompany the supplemental budget.

Even though no supplemental budget is submitted at the time of the July review, SAs should continue to check their expenditure rate for the balance of the fiscal year. An end of year reconciliation and balancing of accounts will occur between HCFA and each State. Actual expenses data will then be
used by HCFA as a basis for setting future fee schedules for the participating laboratories.

6484. NEED FOR ADDITIONAL CLIA FUNDS - SA PROCEDURES

Periodically, the SA should check its current rate of expenditure. If it appears that expenditures may exceed the budget approved or the current allotment, it should consult with the RO. The SA should take full advantage of line-item flexibility (See §6434) before concluding that additional funds are needed.

A. Adjustment in Quarterly Allotments.--During the first three quarters of the fiscal year (October - June), if the SA concludes that expenditures will exceed the current allotment, it submits an informational statement to the RO. This statement should explain in which line-items the SA believes additional funds are needed and give its reason(s) for this conclusion. The SA requests an adjustment in the quarterly allotment schedule to make additional funds available at this time and submits a supplemental budget when it appears funds will be exhausted before the close of the fourth quarter of the fiscal year.

B. Supplemental Budgets.--At the beginning of July of each year, the SA reviews its fiscal requirements for the balance of the fiscal year. If at this time it appears that additional funds are required, the SA submits a supplemental budget that should be completed for the full fiscal year, and include a statement explaining the anticipated shortfall for each category and the net additional amount needed. The SA prepares the supplemental request on the same form(s) and in the same number of copies as a regular budget request and includes supporting information comparable to the kind found on regular requests.

Even though no supplemental budget may need to be submitted at the time of the July review, the SA continues to check its expenditure rate for the balance of the fiscal year.

6486. STATE AGENCY ACCOUNTS AND REPORTING

The SA ensures that all estimates and reports of expenditures and other reports are prepared in accordance with appropriate budgetary and accounting methods and administrative practices adopted by the Secretary.

It is HCFA's desire and intent to accept State practice in the manner in which funds received from the Federal government are handled and accounted for, and in a State's choice of a depository, subject to the general accountability required under Section C, Fiscal, of the agreement. However, funds advanced to a State must be identifiable on a State's records. This is usually done by establishing a separate account. The Fiscal and Reports Sections, along with instructions established by HCFA for receiving advances of funds and submitting reports, have been drafted with a view to following State patterns to the fullest extent possible.

6488. SUPPORT FOR EXPENDITURES - SA PROCEDURES

The SA must provide, through SA accounting and statistical records, support for all expenditures incurred in connection with survey and certification activities. No particular kind of accounting record, method or procedure is required. The State's accounting records and supporting documents must permit verification by Federal fiscal audit and HCFA administrative review of all charges, together with the status of the advances made to the State.

If the SA is receiving grants-in-aid administered by HHS in connection with its regular program, it uses the accounting and procurement methods and procedures described in SA approved plan for such grant-in-aid programs. The SA is responsible for securing the necessary data from local or district offices, and assuring the validity of all data used for budgetary and other purposes.

6490. CERTIFICATE OF AUTHORITY - SA PROCEDURES

A certificate is placed on file with HCFA stating the official title of the State person authorized to submit an estimate of funds, to certify fiscal documents and to represent the SA in fiscal matters.

The SA forwards two copies of the certificate to the RO. If the authority passes to a new office, or the scope of the authorization is changed, the SA submits a new certificate.

6492. CASH BASIS - SA PROCEDURES

The method of financial reporting recommended is the "cash basis." Thus, the data is based upon "cash accounting" which requires that charges against HCFA CLIA funds be entered on SA records when formal vouchers, electronic transactions or other documents that may initiate payment are prepared.

6494. LIMIT ON EXPENDITURES - SA PROCEDURES

The total amount approved in the SA annual budget shall be the limit on expenditures for the fiscal year.

6496. PERIODIC ANALYSIS OF ACCOUNTS - SA PROCEDURES

Since total expenditures for a fiscal year may not exceed the amount approved for that period, the SA reviews the status of accounts at least once each month. This allows the SA to observe expenditure trends as they occur and helps the SA to avoid both over-expenditure of funds and over-accumulation of large amounts of unliquidated obligations. It also provides early identification of any need for supplemental funds.

6498. CASH BALANCES AND EXPENDITURE AUTHORITY - SA PROCEDURES

Unexpended funds on hand at the end of each quarter are available for expenditure in the succeeding quarter without formal reallotment. This is applicable even if the succeeding quarter is in a new fiscal year. This provision applies to all funds on hand whether they were received in a HCFA advance or from other sources. Formal reallotment is not a prerequisite for expenditure of any funds on hand.

6500. UNLIQUIDATED OBLIGATIONS - SA PROCEDURES

Fiscal controls should provide current information on unliquidated obligations. For purposes of HCFA financial reporting, unliquidated obligations are defined as bills received, but not yet prepared for transmission to the State fiscal officer for payment, or obligations incurred for which there is acceptable evidence of a commitment or promise to pay for goods, facilities, or services in any category of expenditure, whether or not the goods or services have been received or a bill rendered. Examples of unliquidated obligations are:

- Equipment which had been ordered, but not paid for (whether or not received); and

- Items charged on a semi-annual or annual basis. For example, for an item charged for an annual basis, the unliquidated obligation reported for the first quarter in the year would represent one quarter of the estimated annual charge. The unliquidated obligation reported in the second quarter would represent one-half of the estimated annual charge. Should the obligation not be paid off at the expected time, the SA continues to report the accumulated amount due.

6502. NOTHING TO REPORT ON A GIVEN LINE - SA PROCEDURES

If there is nothing to report on a given line, the SA should so indicate by the use of a dash (--) or a zero (0).

6504. SA FORWARDING MATERIALS TO THE RO

The RO may request that the SA forward documentation to the RO supporting the SA laboratory survey-related activities. If required to do so, the SA retains a copy of the materials for SA records and sends the original to the RO. Copies of all material must be legible and must contain the appropriate signatures.

6506. STATE AGENCY FILES USED FOR CASE CONTROL AND REPORTING

The RO may also need more specific information about some aspect of SA CLIA operations, or may need other special tabulations and reports concerning an area of program activity. RO may need:

- o The number of applications pending for various lengths of time;
- o Laboratory survey schedules; and
- o The progress made through consultation with a facility.

The SA may use this additional data for SA own purposes as well. All such data is to be readily available from SA records.

Many States are employing their own unique filing system and finding improved methods of control and ways of incorporating additional data such as licensure information, details on the improvements in the quality of service through consultative efforts. The SA may use any technique as long as it affords a positive control over pending cases and provides for adequate tallying and documentation of certification activities. The data extracted from the system for RO reports is rudimentary and easily tallied. Therefore, the case control system probably does not warrant employing data processing equipment. In some cases, the SA already use data storage and retrieval equipment, so it would actually be less expensive and simpler to employ existing equipment than to use a manual case control system.

6508. SA ESTABLISHMENT OF CASE CONTROLS

It is of utmost importance that the SA initiate and maintain proper workload controls. A good workload control system helps to encourage good management practices. Though this section uses the word "system" to describe a mechanism that can help track workload pending and accomplishments, it does not arbitrarily categorize such as a computer-based control system. A simple manual case control system may be something as unsophisticated as a card system that can be used to track the progress of each CLIA workload. Most States already have control systems in place which track other programmatic (survey) workloads. Many are quite sophisticated and computerized. Similar mechanisms may be adapted to CLIA or new more responsive systems may need to be designed to accommodate the CLIA workload. The type of physical system used is less important than the actual capture of the basic information needed to establish and maintain management control over the workload. The SA should make sure any control system considered, whether manual or automated, is able to facilitate the establishment, update and storage of the basic control data. It must also provide the controls that allow for management of pending workloads, laboratories to be surveyed, resurveyed, and hearings pending. Data retention capability should be for a minimum of three years.

6510. PAYMENT BY ELECTRONIC TRANSFER OF FUNDS - SA PROCEDURES

All State agencies with an approved budget will be paid by electronic transfer of funds through the use of DHHS, Division of Federal Assistance Financing's Payment Management System known as SMARTLINK II. The SMARTLINK II User's Manual (Exhibit 121) details the equipment the SA need to implement the system, provides guidelines for maintaining security to the system and explains how the SA request payment using the system. It also provides the information the SA need about installing the DHHS-supplied KERMIT communications package and other system specific procedures.

6512. STATE EXPENSE REPORTING

The Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578, requires that certification fees be sufficient to cover the costs of implementing and administering this oversight program. There are no exceptions. Funds to run the program come from billing laboratories for all costs related to administering all aspects of the CLIA program, including payment of all Federal and State CLIA-related program expenditures. The SA is entitled to receive advances to and payment of all "reasonable costs" for performing CLIA-related work, including the cost of the personnel required to perform the CLIA-related work. CLIA funds cannot be used to pay the SA for any non-CLIA-related expenses incurred. To administer the CLIA program, it is probable that each SA will employ CLIA dedicated staff. CLIA laboratory compliance surveys will be performed by CLIA approved and dedicated surveyors. Though CLIA dedicated support staff will better facilitate the computation of CLIA related expenses for budgeting purposes, it is possible that shared staff involved in supporting multiple programs may be employed. CLIA will pay States only for CLIA-related expenses, so proper proration of expenses is mandatory.

"Reasonable costs" include all necessary expenses that are in accord with these standards and within the limits of the approved SA CLIA budget. Any class or kind of administrative expenditure that is properly chargeable to Federal CLIA funds under plans approved by the DHHS will be funded by CLIA revenues. Allowable costs are further defined in OMB Circular A-102, Cost Principles for State and Local Governments (Exhibit 122). The SA should exercise due care in the expenditure of funds, understanding that the funds must be used only for CLIA-approved activities and procurement.

The completed SA Budget Request, Form HCFA-102 (Exhibit 116), is to accompany the Planned Workload Report, Form HCFA-105 (Exhibit 119), and the budget plan and documentation, as a budget request package that is forwarded to the RO in response to the yearly Budget Call Letter. The HCFA-102 line items are addressed in general and specifically in the following procedures.

6514. EMPLOYEE SALARIES AND WAGES--THE DISTRIBUTION OF STAFF TIME FOR PROGRAM PURPOSES - SA PROCEDURES

CLIA funds are to be used only to pay CLIA program expenditures. However, it is recognized that some personnel may be involved in multiple program activities. Though the magnitude and scope of the CLIA program is such that time-sharing may not occur or even be readily possible, it may by necessity, occur. Thus, an important administrative goal must be to assure that a method for capturing the appropriate work-power split by program is developed, when such time-sharing occurs. The SA should employ the approved methods for determining the proper pro-rata splits and document them to facilitate budget preparation, approval, and execution. It is necessary for the SA to distribute shared staff time to the appropriate separate program areas of State activity.

In the event staff is shared and a cost proration is necessary to determine the related costs for each program, a prorated portion of the cost of such studies, work sampling, data recording, and reporting is a necessary CLIA-related expense. Studies determined necessary or requested by the RO are a necessary and reasonable CLIA expense.

6516. DETERMINATION OF NECESSARY STAFF - SA PROCEDURES

The SA may use the following method to determine a proper split of costs for CLIA versus other State program administration costs. The SA should determine the number of surveys that are planned for each program and determine the amount of staff needed for CLIA surveys and survey-related activity. Workload plans should fulfill the specific requirements of the CLIA laboratory survey program. The SA determines commonly shared staff and estimates the staff requirements for each program. The ratio of countable CLIA activities to the sum total of the countable activities of all programs can be applied to the cost of the total multi-program activity. Using the ratio derived is

acceptable when miscellaneous costs cannot be specifically identified as a CLIA or other program-specific expense. However, the SA should develop specific applications of this general principle jointly with the RO, to allow for circumstances a particular agency may encounter, and ensure the comparability of such activities between programs. Such tools for deriving SA staffing estimates must be approved by the RO before charges for payment can be made. Studies may be conducted to verify the comparability of the activities or to validate the proposed formula for adjustments made in charging expenses to CLIA.

6518. RETIREMENT CONTRIBUTIONS AND FRINGE BENEFITS - SA PROCEDURES

Retirement benefits and fringe benefits that are reasonable costs and in accordance with State and Federal laws are acceptable and payable under CLIA.

6520. TRAVEL - SA PROCEDURES

The cost of travel, including, where appropriate, per diem, or subsistence in lieu of per diem, is charged to CLIA in accordance with provisions of State law, regulations, and administrative procedure applicable to travel of State employees.

A. CLIA Laboratory Survey and Administrative Travel.--Laboratory survey travel includes travel to a facility:

- To conduct laboratory surveys;
- For re-visits or recontacts with a facility about compliance action items, or plans of actions;
- To perform laboratory complaint or oversight surveys; and
- For meetings with HCFA personnel on CLIA-related activities.

Administrative travel is defined as travel within the State:

- For management purposes related to the CLIA laboratory survey program;
- To attend agency administrative staff meetings related to CLIA;
- To attend State CLIA program meetings or activities conducted or sponsored by HCFA; and
- For planning or liaison visits to other agencies having to do with certification.

Travel to participate in sanction meetings or negotiations, or to appear before a ALJ in a Hearing (to provide testimony or support for a sanction activity against an alleged non-compliant laboratory) may also be charged to CLIA.

B. Travel Involving Multiple Program Activities.--Travel expenses for an employee performing multiple program activities (Medicare/Medicaid and CLIA) for the State is to be prorated on the basis of direct personal service based upon time spent on each program involved in and recorded for each trip. Alternatively, such trip records may be accumulated for an accounting period and prorated accordingly. For example, if at the end of the period records showed that 2/3 of the employee's productive time while in travel status was devoted to the Medicare/Medicaid survey and certification program, and 1/3 of the time devoted to CLIA activities, then the agency would charge 1/3 of the total travel cost to CLIA (including transportation, per diem) and the other 2/3 to the Medicare/Medicaid survey and certification program funds.

C. Training and Conference Travel.--This category includes travel not directly related to the line operations of inspecting laboratories, consultation, and administration, as described above. Examples are travel performed (1) Incident to orientation and basic training of new employees in areas appropriate to SA activities in the laboratory survey and certification program; and (2) For meeting the needs of experienced employees for retraining. Also included is travel relating to conferences, meetings, training institutes, workshops, and seminars if the agenda material is directly related to the laboratory survey functions of the agency. Travel for such purposes may be funded by CLIA.

6522. COMMUNICATIONS AND SUPPLIES - SA PROCEDURES

A. Communications.--Telephone services chargeable to CLIA include:

- o Teleconferences;
- o Telegraph messages (except such items as are payable on travel expense accounts);
- o Postage;
- o Postage meter charges;
- o Printed stamped envelopes;
- o Registry and special delivery or express mail fees;
- o Insurance charges on fourth class mail; or
- o Postage due charges incurred by CLIA employees and for CLIA program-related activities.

For services such as satellite training or conferences, contact the RO to determine if the expense is a "reasonable" expense that is payable in accordance with the CLIA-approved budget. Expenses for mobile phones, modems, FAX machines and other communication-related expenses may, in some instances, be justifiable, and, thus, chargeable to CLIA in accordance with the previously approved budget. The SA should consult with the RO to assure payment.

B. Supplies.--The following items are chargeable to CLIA if they are used to support CLIA personnel and CLIA-related activities:

- o General office supplies such as paper, pencils, folders, unstamped envelopes, clips;
- o Non-consumable supplies such as staplers, pencil sharpeners, file baskets, books, which do not exceed a $50 per unit cost;
- o Printing and duplicating expense and the cost of procuring forms such as printed or duplicated general office forms; and
- o Costs of transportation or shipment of any of the above items.

The $50 unit cost for non-consumable items shall apply unless a different amount is specified by State law, in which case the amount so specified shall control. If purchases are commingled with other than CLIA program purchases of the same nature, the SA documents and justifies the expenses on a prorated basis.

C. Basis for Charges.--Communications and supplies should be direct CLIA charges if separable from other program costs and identifiable as to unit cost. The SA charges these expenses on a prorated basis if used for multiple program purposes. For example, if long distance calls are routed through a switchboard or can otherwise be identified as to program, the CLIA calls can be made a direct charge. Otherwise, all long distance charges are to be prorated, using an identifiable and justifiable method or formula. It would not be equitable to charge the CLIA program for installation and rental of telephones used exclusively by other State staff. If lines and telephones are shared by CLIA and non-CLIA personnel, payment is computed on a pro-rata basis. If an employee is engaged in multiple program activities, including CLIA-related activities, CLIA is to be billed only on a prorated share basis. The SA includes the documentation of the method of proration or the formula used.

6524. OFFICE SPACE - SA PROCEDURES

The cost of office space essential for CLIA laboratory survey functions is a proper charge against CLIA funds. The rules governing all such rentals and leases are the same for CLIA as they are for all other HCFA rentals and leases. These guidelines replicate those rules and guidelines. Such charges may take the form of:

- Rent, service, and maintenance cost in privately-owned buildings;
- Monthly rental charges based on the cost of initial construction or purchase of publicly-owned buildings; and
- Meeting the costs of service and maintenance in lieu of rent in publicly-owned buildings.

In addition, charges may be made for repairs and alterations to either privately or publicly-owned buildings. Payment will be made only for periods of occupancy unless approval is received from HCFA for payment for periods of nonoccupancy.

Charges against CLIA funds for office space must follow other HCFA guidelines and thus, may not exceed the rental rate of comparable privately-owned space in the same or similar locality. Although the rental rate of comparable privately owned space is not a fixed amount for any particular locality, and the rental rates may vary within a locality as well as between localities, it is expected that a realistic determination of the rental rate of comparable privately-owned space be made. The basis and documentation for establishing the rental rate of comparable privately-owned space is to be kept on file.

6526. PRIVATELY-OWNED SPACE - SA PROCEDURES

Charges against CLIA funds for privately-owned space, including expenses of services and maintenance, repairs, and alterations, must not exceed the rental rate of equivalent space and facilities in the same or similar locality.

In negotiating a lease for privately-owned space, the SA includes cancellation or conditional clauses in rental agreements. The following guides are applicable with respect to the rental of space in privately-owned buildings when renewing an existing lease or when obtaining new or additional space under a lease:

A. Cancellation Clause.--When executing or renewing leases, the SA should make every effort to include a reasonable right of cancellation (30 days, if possible) in favor of the State, if such right can be included in light of rental rates, probable permanency of occupancy, and other pertinent factors. The SA should attempt to secure a cancellation clause in all rental agreements covering space for more than 1 year.

B. Lease Not Exceeding One Year.--When the SA is unsuccessful in securing a cancellation clause, it should make an attempt to secure leases not to exceed 1 year's duration, if possible, with an annual renewal option for an extended period, such as 3 years or longer.

C. Consulting the RO.--Where neither of the above is possible, the SA consults the RO at least 30 days in advance of the date the lease is to be signed.

6528. SPACE IN PUBLICLY-OWNED BUILDINGS - SA PROCEDURES

The following standards apply to charges for office space in a publicly-owned building:

A. Actual Cost.--The amount charged for office space in a publicly-owned building must not exceed actual costs over a long-run period. The SA is required to produce records of actual costs for examination as necessary. The SA will:

o Not include the cost of land as part of the cost of initial construction or the purchase of publicly-owned buildings in deriving the rental charges. This exclusion is based on the fact that land has no actual physical depreciation. The State would always have the land as an asset long after the building had become obsolete or been demolished, and value could be realized.

o Establish the estimated useful life of the building if depreciation is included as an element of cost. In case the building is vacated before the end of its useful life, adjust past claims for amortization to a reasonable depreciation basis.

B. Cost After Building Amortization.--After the initial cost of a building has been amortized, the SA charges only the costs of service and maintenance.

C. 75% Rule.--The amount charged for office space in a publicly-owned building may not exceed 75% of the lowest comparable rental for privately-owned space unless there are special considerations justifying a greater charge. The use of this standard as an expedient interim measure in the absence of actual cost data, enables the SA to claim costs that are not in excess of 75% of the lowest cost of privately-owned space without prior review or approval by the RO.

D. Ratio of Charge-to-Rental Rates in Privately-owned Space.--Experience gained in analyzing the elements of rental rates in privately-owned space shows that approximately 75% of the rate represents the expense of service, maintenance, and depreciation. The portion in excess of 75% of the rental rate of comparable privately-owned space generally represents taxes and profit on investment that would ordinarily accrue. Therefore, whenever a charge is made for space in a publicly-owned building that is not in excess of 75% of the lowest cost of comparable privately-owned space in the same or similar locality, the SA assumes that such charge is reasonably related to the expense of service, maintenance, and depreciation. The SA verifies the reasonable relationship of such charges to actual costs over a long-run period. When a monthly rental charge based on the cost of initial construction or purchase of publicly-owned buildings exceeds 75% of lowest comparable rental for privately-owned space or when the cost of service and maintenance in lieu of rent in publicly-owned buildings exceeds 75%, the SA obtains prior approval from HCFA.

E. Charge Based on Cost of Initial Construction or Purchase.--When rental charges are based on costs of initial construction or purchase of a publicly-owned building and such charges exceed 75% of the lowest comparable rent for privately-owned space, the SA submits justification for review and approval by HCFA prior to acquisition or occupancy of the space.

F. Charges Based on Meeting the Cost of Service and Maintenance.--When the total charges for service and maintenance in a publicly-owned building exceed 75% of the lowest comparable rental for privately-owned space, prior to the SA's claim, the SA submits the following data for review and approval by HCFA:

- o Total useable floor space and the amount of space allocated to the CLIA laboratory survey program personnel;
- o Total costs of service and maintenance and the portion to be charged to CLIA funds;
- o The elements of cost; and
- o The rental cost of comparable privately owned space, with at least three statements of appraisals.

6530. REPAIRS AND ALTERATIONS - SA PROCEDURES

Charges may be made for repairs and alterations in privately or publicly-owned space necessary to the maintenance of proper facilities for efficient administration of the State survey unit.

A. Maintenance Repairs.--The SA includes maintenance repairs such as painting, repairs to plaster, patching roofs and minor repairs to doors, elevators and electrical equipment in the rate for service and maintenance.

B. Major Repairs and Replacements.--Major repairs and replacements, such as structural changes in buildings, new roofs, and new heating systems may be amortized over a period of years provided the total cost for space on an annual basis does not exceed lowest comparable rental, or in the case of publicly-owned buildings, 75% of the lowest comparable rental for privately-owned space. If the cost is amortized, the repairs and alterations must be of a permanent nature. Repairs and alterations which remain the property of the agency are usually classified as moveable equipment.

C. Alterations.--Normally, quarters completely adequate for the SA should be obtainable from the lessor, and the cost of necessary alterations would be borne by the landlord. However, where the landlord is unwilling to bear the cost of necessary alterations, HCFA funds can be authorized to meet the cost of alterations provided the proposed alterations are needed for better utilization of the space, and the improvements are not obligations of the lessor under the terms of the lease. In some situations, lessors will not agree to make necessary alterations but will offer space at a relatively low rental rate. In such cases, the SA should try to negotiate an arrangement under which the lessor would make necessary alterations and the SA would amortize the cost by an increase in rent for a stipulated length of time. Before agreeing to an arrangement providing for repair or alteration, the SA should secure approval from the RO.

6532. IDENTIFIABLE (DIRECT) COSTS - SA PROCEDURES

When locating program personnel in extra identifiable space, the SA charges CLIA for the cost of such space.

Where SA CLIA program personnel share space with the SA regular personnel, the SA apportions the cost of such space between the programs. The apportionment is based upon the SA proration plan and must be approved by HCFA. The method approved will apply only to rental fees paid for locations where SA program personnel share occupancy. The SA should re-evaluate the basis for prorating rental costs when changes in physical facilities or other conditions may result in inequitable cost sharing.

The SA submits the SA's rental cost apportionment plan each year as part of the budget documentation. Approval of the budget constitutes approval of the plan of apportionment.

6534. OFFICE MAINTENANCE - SA PROCEDURES

A. Definition.--Office maintenance includes services such as light, heat, time clock and water service, towel and janitor service, and machine repair service prorated on the same basis as rent, provided such services are not already included in rental costs.

B. Basis for Charges.--If associated office maintenance costs, in whole or in part, are included in the SA's rental contract, the SA does not separate them; however, it notes their inclusion. The SA charges maintenance costs which are not included in rentals on the same basis as rental costs.

6536. EQUIPMENT - SA PROCEDURES

A. Definition and Quality of Office Equipment.--Items which are of a non-expendable nature, i.e., they have a life expectancy of one year or more and a probable resale, salvage, or trade-in value, are classified as office equipment if they have a unit cost in excess of $50. However, if a different amount is specified by State law, the amount so specified shall apply. The quality of items should not exceed the quality of similar office equipment in general use in other SA offices.

B. Title to and Accountability.--Title to and accountability for office equipment purchased for State survey program purposes, or for shared use with other State or Federal programs, shall rest with the State. However, the purchase price(s) of individual pieces of office equipment may be shared with other State or Federal programs. Where the costs of equipment are prorated between Medicare and other programs such as CLIA, the SA should use the same proration in crediting residual value to the Medicare, or CLIA program for all disposed equipment. Where Medicare-only, CLIA-only, or Medicaid-only funds are used to fully fund equipment, the SA credits 100 percent of the residual value to the appropriate funding program, either Medicare, Medicaid or CLIA, but not all.

C. Purchase of Equipment.

1. State Practice.--The SA follows established State law or regulations for procurement of equipment for the State survey program.

2. Purchases Related to Budget Process.--Funds for equipment purchases are to be requested by State agencies and approved by HCFA as part of the budget process. The SA should try to predict SA equipment needs during pre-budget planning, and request all needed equipment in the budget submittal. To estimate equipment needs, the SA determines the condition of equipment on hand and the appropriateness of the equipment for the tasks to be performed. The SA should also consider proposed staffing increases in SA budget projections.

The total expended for equipment during the budget period cannot exceed the total funds allocated for equipment for that period without prior approval of the RO.

3. Items Deleted by HCFA.--After reviewing an agency's estimate for equipment, HCFA may delete an item or restrict the purchase of an item. If upon review of the HCFA deletions, the SA want to resubmit the request it should do so. The SA submits the request with added supporting information. However, until the restriction is removed, the item cannot be purchased with Federal funds.

4. Purchase of Items Not Included in Budget Submittal.--Althoughthe SA is expected to anticipate the bulk of its equipment needs, the SA may occasionally find a need for equipment that was not included in its budget submittal. The SA must secure approval of the RO before purchasing such items of equipment. However, if sufficient uncommitted funds are available, the SA may purchase items not included in the budget approval without prior RO approval when the unit cost of the item is $50 or less, and the item is of a kind approved in any previous budget period, e.g., tables,

chairs, coat racks. The SA lists such items and identifies them in the equipment schedule submitted at the end of the quarter in which purchased.

5. Reporting Equipment.--The SA maintains an inventory of equipment, following usual State inventory practices, and make an annual physical count of equipment items for comparison against the inventory records. In the event of equipment loss or substantial damages due to theft or fire, the SA submits a statement concerning such losses to the RO as soon as possible.

D. Rental of Equipment.--Situations may occur where it will be advisable to rent certain office equipment instead of purchasing it. The rental of office equipment is allowable if it is not contrary to State law or regulations. Expenditures for equipment rental are considered "necessary" if:

- o The rental is for a short period of time;
- o The equipment is not available for purchase (leased telephone lines, electrostatic photocopy machines, etc.); or
- o It can be shown that renting rather than purchasing an item of equipment is advantageous in terms of cost.

Secure prior approval from the RO if the SA wishes to rent equipment for more than 90 days.

6538. RETIREMENT AND SOCIAL SECURITY - SA PROCEDURES

A. Retirement Contributions.--Retirement contributions include SA cost (not employees' share) of contributions to retirement funds such as State retirement or social security.

B. Prorating Costs.--Where SA prorate personal services costs of State survey personnel, it prorates the retirement costs for these personnel.

6540. OTHER EXPENSES - SA PROCEDURES

"Other" expenses include expenditures which can be properly charged to the State survey program, but have not been provided for in any of the preceding classifications. Examples of such items are discussed below by category.

6542. CONSULTANTS - SA PROCEDURES

Consultant services are generally defined as being furnished by persons who are not State employees, but who will be used on a part-time, temporary, or fee-for-service basis to provide needed skills to the State survey program.

6544. TRAINING OF STATE AGENCY PERSONNEL - SA PROCEDURES

The reasonable costs of training personnel engaged in CLIA survey and related activities are chargeable to the CLIA program when the training is related to its responsibility for survey, certification and related enforcement activities.

Training may include attendance at job-related meetings, conferences, seminars, workshops, satellite training conferences or training courses. Training is to be related to SA CLIA-related responsibilities. Examples of professional meetings for which attendance may be justified and funded, subject to prior RO approval are periodic and annual meetings of regional or national laboratory and medical technologist professional societies and organizations such as, but not limited to, the American

Society of Clinical Pathologists (ASCP), the American Society of Medical Technologists (ASMT), American Clinical Laboratory Association (ACLA), American Society for Cytotechnology (ASC), College of American Pathologists (CAP), and the Clinical Laboratory Management Association (CLMA).

A. Funding.--HCFA will fund the entire cost of approved training of all employees. Funding for SA training is subject to the following considerations:

o Out-of-State attendance must be in accord with established State rules and regulations.

NOTE: When Federal requirements mandate that the training is necessary, SA travel policy for out-of-State travel is not an excuse for non-participation in the Federal training.

o Federal funds may not be used to attend any meetings or events if the attendee is paid by the sponsoring organization to attend or to speak or render other services in connection with the meeting.

o Attendance will not significantly impair work activities.

B. Requesting Approval.--Funds for conferences and short-term training activity is normally requested, in advance, in the annual budget submittal. The SA submits any training that has not received prior HCFA approval in the approved budget, in advance, to the RO for approval. Approval is to be on a case-by-case basis.

At the SA's request, HCFA will include a dollar authorization for short-term training activity over and above the cost of attendance at HCFA-sponsored meetings within the funds approved for each fiscal year. This authorization covers travel, per diem, admission fees, and any other costs related to attendance at the meetings.

If the SA believes it necessary to exceed the allotment, see §6546. The SA can make expenditures for short-term training activities without consulting the RO for specific authorization provided the following conditions are met:

o No single meeting is attended for more than 5 working days;

o The proposed attendees are State CLIA employees who regularly perform CLIA-related functions;

o The training is related to your CLIA-related responsibilities;

o The SAs do not charge a higher percentage of the cost of the CLIA-related portion than is appropriate. The appropriate portion attributable to Medicare/Medicaid or other programs is to be charged to those programs;

o A Form HCFA-102 (Exhibit 116) is submitted as a supplemental budget request, in advance, if the event was not previously approved in the budget process. If the employee entered on duty during that quarter or later, the SA charges the percentage applicable to the employee in the budget approval; and

o Ensures that there is adequate documentation of every expenditure, following State practice, for subsequent audit.

Where one or more of the preceding conditions are not met with respect to any particular meeting, the SA furnishs detailed justification well in advance of the planned training/event date.

The authorization of funds for short-term training is in addition to the cost of attending any meetings called by HCFA. The SA should consult with the RO for budget information about proposed HCFA meetings as part of the process of preparing the budget submittal.

C. Justification for Attendance.--Where it is necessary to furnish detailed justification for attendance at short-term meetings, either in the original budget or later on in the fiscal year to the RO, (because, for example, the criteria in subsection B above are not met or the allotment is exhausted), the SA provides the following information:

- o Name, position and title of each person proposed for attendance;
- o A list of previous out-of-State training meetings attended by each proposed attendee during the current fiscal year (other than HCFA-sponsored meetings) which were charged to Federal funds;
- o An itemized listing of proposed expenditures for attendance, including travel, per diem, and admission fees; and
- o Name, location, and dates of the meeting and a copy of the course announcement or bulletin, if available. Also, the SA submits a copy of the agenda or a list of the subject matter on the agenda and the name and address of the sponsoring organization. Where the description of the subject matter does not clearly establish that it relates to CLIA responsibilities, the SA provides an explanation of how the subject matter relates to CLIA responsibilities.

D. Fiscal and Reporting Considerations-The Amount Requested for Travel Costs of Such Activity.--The SA shows the total amount approved on the SA Budget Notice of Approval, Form HCFA-104 (Exhibit 118), for the CLIA program (the HCFA-435 for the Medicare and Medicaid programs).

The SA does not break down the amounts expended for specific meetings, conferences or events. However, the SA maintains detailed records of all expenditures for audit purposes.

E. Educational and Training Leave.--Educational leave is leave granted for specialized professional or technical study in an accredited educational institution. Training leave is leave granted to an employee for attendance at short-term courses that will run longer than 5 working days, outside the agency. Approval of educational or training leave can only be granted if it is for purposes related to carrying out CLIA responsibilities. Additionally, State rules, regulations and practice must permit the taking of leave for such purposes. The SA obtains approval of training or educational leave, in advance, from the RO. Such proposals are evaluated individually and specific circumstances and special problems are given proper consideration. The SA includes the following in its requests:

- o Employee's name, type of appointment held, position and grade (salary), length of service with the SA, previous experience and education;
- o Description of any other specialized training or courses taken by the employee within the previous 24 months;
- o Name and location of training institution;
- o Title and description of training in sufficient detail to demonstrate its scope, content, and how it relates to CLIA responsibilities. A copy of the training course announcement may help to fulfill this requirement;
- o A statement indicating how this training will benefit the employee's work and improve the agency's activity;

- The training period showing the number of days and hours the employee will be absent from duty;

- A statement from the supervisor dealing with the ability of the unit to forego the services of the trainee during the training period; and

- The cost of tuition, fees, books in detail. A copy of the training course announcement may help to fulfill this requirement.

F. Agreements by Employees to Continue on the Job.--In order to discourage resignation of an employee for whom there has been a considerable expenditure for formal training, some States require the employee to sign an agreement that she/he will remain on the job for a certain length of time (e.g., 6 months) after completing the training. If State regulation or practice provide for such agreements, the SA has the selected employee sign such an agreement after having obtained HCFA approval for the activity.

6546. MISCELLANEOUS - SA PROCEDURES

Items illustrative of this category, for example, are:

- Bonding and public liability;

- Equipment rental;

- SA cost (not employee's share) of workmen's compensation;

- Group insurance;

- Unemployment insurance; and

- Proportionate share of merit system of civil service charges.

Multi-program proration of costs always applies.

A. Bonding.--Where a new bond or an amendment to an existing bond is required in relation to receiving and handling CLIA funds, the cost of the bond, when borne by the State, or the additional cost attributable to an amended bond, is a proper charge.

B. Public Liability.--An appropriate share of the cost to protect against financial responsibility for injury to person or property is properly charged to HCFA when such expenses are in the form of premiums for public liability or property damage insurance. The cost of awards, judgments, or settlements arising from injury to person or property are not chargeable to HCFA.

The share of public liability and property damage insurance costs properly chargeable to HCFA, in the case of motor pool or personally-owned vehicles used in the discharge of SA official business, is proportionate to that share of all travel of personnel of the agency which is devoted to activities directly concerned with the CLIA program.

The other items mentioned above may be prorated or charged directly as appropriate. If prorated, the method of prorating should be appropriate and acceptable to the State and to HCFA. Thus, the costs of workmen's compensation, group insurance, or unemployment insurance would usually be charged directly for employees whose salary costs are prorated in the same ratio as the salary costs.

6548. GOODS, FACILITIES, SERVICES FROM OTHER STAFF OR LOCAL AGENCIES

A. Definition.--The definitions of the terms "goods," "facilities," and "services" and the criteria for application of the standards are those in effect for SA grant-in-aid relationship with the Department of Health and Human Services.

B. Centralized State Services.--In some States services of an administrative nature (including certain commodities) such as accounting, printing, civil service, or central purchasing are furnished to various operating agencies of the State by specialized service departments outside the health department or other agency having an agreement or State plan with DHHS under §§1864 or 1903 of the Act. The SA allocates an equitable part of such charge to the State CLIA program if the services are necessary and are ones from which the program derives a benefit similar to that accruing to other units of the agency, and provided:

- The pro rata charge to the CLIA program does not include costs attributable to the general expense of State government in carrying out the coordinating, fiscal, and administrative functions of government;
- The charge is based on reasonable cost; and
- The costs are extra, identifiable, and readily ascertainable either by segregation or as a prorated share of the cost of such facilities or services.

The SA describes the basis of the service agency's charge, including the method of proration and the services provided and submits it for prior approval. The SA identifies such costs separately in the CLIA budget submittal.